FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

10-05
7 December 2005

FINAL ASSESSMENT REPORT

APPLICATION A470

FORMULATED BEVERAGES

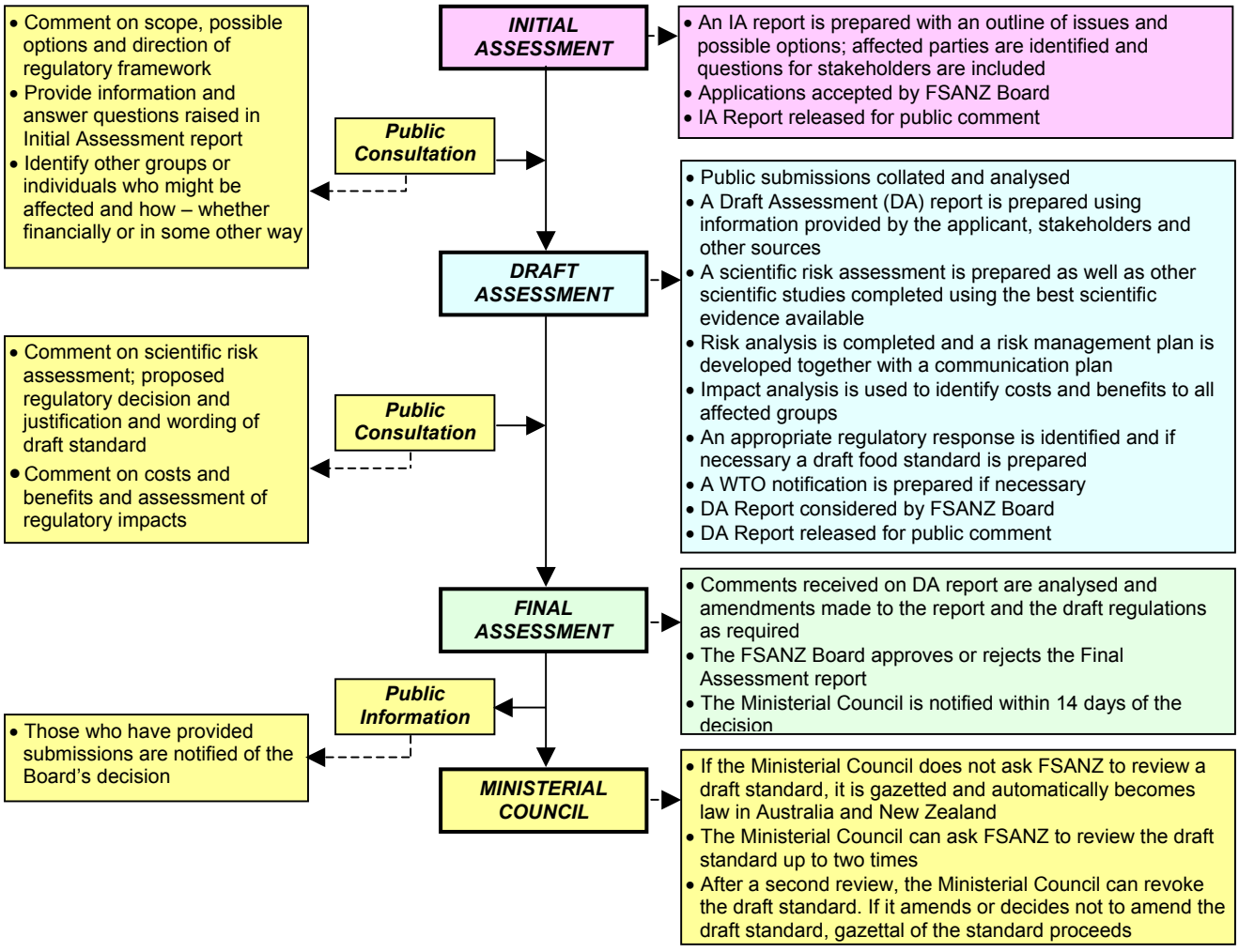
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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.



Final Assessment Stage

FSANZ has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Management Officer at 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

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

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Executive Summary and Statement of Reasons

Food Standards Australia New Zealand (FSANZ) is amending the *Australia New Zealand Food Standards Code* (the Code) to create a category of beverages: formulated beverages, with permissions for the addition of up to 16 vitamins and minerals and compositional criteria of a maximum 24% fruit ingredients and 7.5 g sugar per 100 ml[1].

Introduction

This Final Assessment assesses an Application from the Australian Beverages Council Limited (formerly the Australasian Soft Drink Association) seeking amendments to the Code to permit the addition of up to 16 vitamins and minerals to, and the use of a range of food additives in formulated beverages.

Formulated beverages are described as non-alcoholic, water-based, flavoured beverages containing claimable amounts of vitamins and minerals.

Regulatory Problem

Currently there are no specific provisions in the Code for the addition of vitamins and minerals to formulated beverages. 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 formulated beverages from over-exposure to some vitamins and minerals and from increased sugar intake. Most consumers would be unaware of any potential risks associated with the consumption of formulated beverages. Hence an assessment of these beverages is essential to protect public health and safety.

In addition, Australian beverage manufacturers are currently unable to manufacture formulated beverages, unless they utilise the existing Formulated Supplementary Sports Foods Standard (Sports Foods Standard). This is inconsistent with the intent of the Sports Foods 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 formulated beverages and sell them in Australia in accordance with the Trans Tasman Mutual Recognition Arrangement (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 is also inconsistent with the intent of the Treaty[2] to create a single set of food regulations in Australia and New Zealand.

Objectives

In the context of FSANZ's statutory objectives, an assessment of 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 formulated beverages;

[1] For the purpose of this report, the term 'sugar' as it relates to formulated beverages refers to total sugars i.e. monosaccharides and disaccharides.

[2] Agreement between the Government of Australia and the Government of New Zealand concerning a joint food standards system, (1995).

- enable consumers to make informed choices about formulated beverages; and
- ensure a regulatory system which promotes efficiency and competitiveness for all sections of the formulated beverages industry.

Risk Assessment

A risk assessment has been conducted to determine the nutritional and safety risks arising from the addition of vitamins and minerals to formulated beverages. Both potential benefits and risks have been considered. A Nutrition Assessment (at Attachment 5) has assessed the potential nutrition and health need for the addition of vitamins and minerals to formulated beverages, and broader nutrition risks associated with formulated beverages. The potential for formulated beverages to result in a health risk from the over-consumption of the requested vitamins and minerals has also been examined (at Attachment 6). The risk assessment concluded that the following vitamins and minerals met both the nutrition and risk assessment criteria for inclusion to formulated beverages: riboflavin; folate; vitamin B6; vitamin D; vitamin E; calcium; iodine; iron; magnesium; and selenium.

Potential risks were identified between sugar-containing beverage intakes and overweight/obesity and dental caries, and between consumption of acidified beverages and dental erosion. To assess whether the risk from consuming sugar-containing beverages was likely to arise in the Australian and New Zealand diets, FSANZ undertook dietary modelling to determine if the consumption of sugar would change significantly with the introduction of formulated beverages. The results show that even under the conservative scenario of formulated beverages substituting for 'like' products, the introduction of formulated beverages into the market is unlikely to further adversely affect public health in relation to sugar intake and obesity, or in relation to sugar intake and dental caries.

A risk assessment has also been conducted to determine the safety risks arising from the addition of food additives to formulated beverages. The nature of any potential hazard and a risk characterisation has been assessed (at Attachment 8). On the basis of currently available information, it can be concluded that the addition of the requested 57 food additives/additive groups to formulated beverages would not raise any public health and safety concerns.

Risk Management

This Final Assessment Report considers, in the context of the findings from the Risk Assessment, a number of issues relevant to the regulation of formulated beverages including:

- issues concerning the purpose, defining elements and the definition of formulated beverages;
- the target market and consumer perceptions of formulated beverages;
- the appropriateness of formulated beverages as a vehicle for voluntary fortification;
- the need for specific labelling requirements for formulated beverages; and
- the technological justification of the requested food additives (as at Attachment 9).

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 formulated beverages in the Code;

- Option 2 – Amend the Code to permit the addition of vitamins and minerals to formulated beverages as requested by the Applicant, with additional specific compositional requirements;

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

Option 2 has been assessed as fulfilling the specific objectives of this Application and providing the greatest net benefits to all affected parties when compared to Options 1 and 3.

Consultation

The Draft Assessment Report for this Application was released for public comment from 25 May to 6 July 2005 (six weeks). A total of 30 submissions were received and are summarised at Attachment 10. The majority of submitters supported Option 2, mainly because of the inequitable trade situation for Australian beverage manufacturers. Most submitters however did so either noting reservations or suggesting modifications to Option 2. Issues raised in submissions are discussed in Attachment 3. A summary of the eight key issues raised in these submissions is provided below.

Summary of FSANZ's Response to Key Issues

What is the purpose and scope of formulated beverages?

FSANZ has classified formulated beverages as general-purpose foods – that is, food that is widely available for consumption by the general community. Formulated beverages have been defined as water-based beverages with compositional criteria of no more than 24% fruit ingredients and 7.5 g of total sugar per 100 ml. Because vitamins and minerals will be added to formulated beverages, it is likely that these products will be marketed and positioned in such a way that highlights them as being 'healthier' alternatives to traditional water-based beverages including soft drinks.

It is anticipated that formulated beverages will be marketed as general-purpose foods as the likely target group do not have particular dietary requirements. Therefore it is appropriate to adopt the same approach to regulating the addition of vitamins and minerals to formulated beverages as other fortified general-purpose foods. This includes applying the Ministerial policy guidance on the fortification of foods with vitamins and minerals.

Some submitters supported an extension of the scope of the application to milk, fruit juice and fruit drink. As these ingredients were not included in the original application they were not considered in this assessment. However, any individual or organisation can make a separate application to FSANZ at any time to have these permissions considered.

Why has a compositional requirement on fruit juice content and total sugar been applied to formulated beverages?

Formulated beverages are likely to be marketed and positioned as 'healthier' alternatives to traditional water-based beverages including soft drinks.

To ensure the integrity of the product range is maintained, specific compositional criteria will be used as defining elements of the formulated beverage category. These criteria will apply to the permitted fruit ingredients and total sugar content. The fruit ingredient limit is to avoid confusion with fruit drinks, a class of drink that has its own approvals for added vitamins and minerals. Similarly, the total sugar compositional requirement will also distinguish formulated beverages from other categories of water-based beverages given these products will be positioned in the market as 'healthier' beverage alternatives.

How has FSANZ addressed the Ministerial policy guideline for voluntary fortification?

The regulatory approach to formulated beverages conforms with Ministerial policy guidance and therefore FSANZ's statutory responsibilities.

FSANZ is obliged to set food standards in accordance with the responsibilities set out in the FSANZ Act including having regard to guidelines that may be issued by the Australia and New Zealand Food Regulation Ministerial Council from time to time. In 2004, the Ministerial Council released a Policy Guideline on the *Fortification of Foods with Vitamins and Minerals*. This applies to mandatory and voluntary fortification.

The Policy Guideline contains both 'High Order' and 'Specific Order' Principles. The 'High Order' Principles reflect FSANZ's statutory obligations which along with FSANZ's three primary objectives[3] include fair-trading, best available scientific evidence, and the desirability of an internationally competitive food industry. The 'High Order' Principles also include the Council of Australian Governments (COAG) principles[4] of minimum effective regulation. 'The 'High Order' Principles take precedence over the 'Specific Order' Principles.

The Policy Guideline states that voluntary fortification can be considered, where there are no safety concerns, on the basis of 'need' (i.e. evidence of deficiency or low intake levels) or potential health benefit from fortification.

FSANZ proposes to permit ten vitamins and minerals on the basis of the 'Specific Order' Principle of 'need', and a further six on the basis that permissions already exist for similar products. For example, the Code already permits the addition of vitamin C, folate and carotene forms of vitamin A to fruit drinks, which can be viewed as fulfilling a similar function. Extending these existing permissions to formulated beverages is consistent with the 'High Order' Principles.

[3] FSANZ's primary objectives 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

[4] 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).

FSANZ's scientific evaluation found no evidence of risk to public health from the use of the sixteen vitamins and minerals in formulated beverages. It also considered the potential impact on broader health issues of using formulated beverages as a food vehicle for voluntary fortification.

Should formulated beverages be used as food vehicles for voluntary fortification?

FSANZ considers it is appropriate to voluntary fortify water-based, flavoured beverages. FSANZ recognises that the nature of a food vehicle can have nutritional consequences, which must be considered when assessing any new proposed voluntary fortification measure. In the case of formulated beverages, the issue of primary concern is the total sugar and energy content of these drinks and possible effects on obesity and dental health.

The Ministerial Policy Guideline states that a 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'. Public health recommendations[5] encourage only moderate sugar intake.

The FSANZ *Fortification Implementation Framework*[6] has guided the assessment of the appropriateness of formulated beverages as a food vehicle for voluntary fortification. This framework was developed in consultation with key stakeholders, including the jurisdictions, and underpins all of FSANZ's fortification assessment work. The framework acknowledges that the introduction of a newly fortified food into the market can result in substitution, displacement, addition or avoidance. FSANZ has concluded, on the basis of the evidence available, that consumers will largely **substitute** formulated beverages for their unfortified counterparts – that is, for other water-based beverages. Furthermore, our very conservative analysis indicates that the introduction of formulated beverages is unlikely to increase sugar intake.

What is FSANZ's role in addressing public health issues?

One of FSANZ's key objectives in protecting public heath and safety[7] is to ensure that the people of Australian and New Zealand have access to a safe and nutritious food supply. FSANZ does this primarily through the development, variation and review of food standards. These standards relate to individual foods and food components. While a varied diet contributes to good nutrition, there are many factors which influence food choice. Therefore food standards alone cannot determine an individual's diet and hence dictate an individual's health status.

Food regulation, in itself, is generally not an effective intervention to address public health issues, particularly issues which are multi-factorial and chronic in nature. However, where appropriate, FSANZ seeks to support, strengthen and complement existing public health initiatives. Primarily this occurs by helping to create supportive environments, for example the use of appropriate food labelling which allows consumers to make informed food choices.

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[5] National Health and Medical Research Council (2003) *Dietary Guidelines for Australian Adults*. Canberra. Ministry of Health (2003) *Food and Nutrition Guidelines for Healthy Adults: A background paper*. Wellington. Ministry of Health.

[6] The Fortification Implementation Framework (May 2005) is available at www.foodstandards.gov.au

[7] Protecting public health and safety refers to the actions taken by society to prevent disease, prolong life and promote health.

Will permissions for formulated beverages have a negative impact on public health?

FSANZ is unaware of any consumer research that has examined the impact of formulated beverages on beverage selection preferences and health status. Consumer research provided by the Applicant and general beverage consumption patterns indicate that the majority of consumers would substitute formulated beverages for 'like' beverages, such as fruit juice drinks and bottled waters, and other non-alcoholic beverages.

Using data from the Australian and New Zealand National Nutrition Surveys, along with grocery tracking information[8], we modelled the impact of formulated beverages on population intakes of total sugar to see what, if any, impact this would have on health.

The results of the dietary modelling, even when using a very conservative 'worst case' scenario[9], shows a minimal impact on total sugar intake. It is therefore very unlikely that the introduction of formulated beverages onto the market will adversely affect public health in relation to sugar intake and obesity, or dental caries. FSANZ's risk assessment also concluded that the risk from dental erosion from the consumption of formulated beverage is minor.

On this basis, FSANZ does not believe that the voluntary fortification permission for formulated beverages will promote consumption patterns inconsistent with nutrition policies and guidelines; increase consumption of foods high in sugar; or impact adversely on health status.

Will consumers be misled about the perceived nutritional benefits of formulated beverages?

This concern focuses on a perception that fortified foods, in general, are healthier than their non-fortified counterparts and that some individuals may underestimate the level of risk-increasing nutrients, such as sugar, in the presence of manufacturers' claims.

FSANZ believes that the generic labelling provisions in the Code (including information contained in nutrient information panels and the ingredients listing), together with the permitted vitamin and minerals claims, should provide consumers with sufficient relevant information. The proposed health claims framework will seek to ensure that the presence of claims on fortified foods will not mislead consumers. This coupled with the compositional requirement on total sugar should enable consumers to assess the appropriateness of a formulated beverage when making food/beverage choices.

Another concern raised by submitters is that of bioavailability and stability – that is, the amount of a vitamin or mineral present in a form that can be used by the body in a biological function. The issue is whether the stated quantity of these nutrients is available to the consumer during the shelf life of formulated beverages.

Since bioavailability varies among nutrients, whether from a natural or synthetic source, FSANZ has decided that formulated beverages will be treated the same as foods with natural sources of vitamins and minerals who wish to make content claims for their products.

[8] AC Nielsen ScanTrack (2005).

[9] 100% substitution scenario whereby formulated beverages at the maximum sugar level, replace all 'like' products, such as fruit juice drinks, carbonated non-alcoholic beverages, cordials, sports drinks and bottled waters (except juices).

How reliable are the data and assumptions in FSANZ's scientific evaluation?

When processing applications, FSANZ uses the best scientific evidence that is currently available, as is required under the FSANZ Act. FSANZ acknowledges all assumptions and limitations of the scientific data when reaching regulatory decisions. The food consumption data used in the modelling is drawn from the latest Australian National Nutrition Survey (1995) and New Zealand National Nutrition Survey (1997).

FSANZ recognises that information from these surveys is up to ten years old. Nevertheless, this information provides the best estimate currently available of actual consumption of foods and the resulting estimated intakes for consumers of food chemicals in Australia and New Zealand. Where significant uncertainties exist in the data used for dietary modelling, conservative assumptions are used to ensure estimated dietary intakes, and therefore the level of risk, are not underestimated. The assumptions made for the dietary exposure assessments for A470 are outlined in Attachment 7 for nutrient modelling and Attachment 8 for food additive modelling.

Where data are less reliable, updated data are sought to improve the assumptions made and the exposure estimates. As no accurate data were available for the consumption of formulated beverages, the non-alcoholic beverage consumption data from National Nutrition Surveys was used. Assumptions are based on data wherever possible. Information on the types of formulated beverages that will be available, and the types of beverages currently consumed that formulated beverages may replace, were sought from the Applicant. A conservative modelling approach was taken, based on information provided by the Applicant, where it was assumed that formulated beverages would replace 'like' products, such as fruit juice drinks, carbonated non-alcoholic beverages, cordials, sports drinks and bottled waters; but would not replace milk products or beverages such as teas, coffees, tap water, fruit juices or alcoholic beverages.

This approach was not valid to assess potential changes in total sugar intakes resulting from consumption of formulated beverages, as many non-alcoholic beverages already contain sugar. Therefore, more up-to-date market share data on non-alcoholic beverage consumption from a 2004 survey was used to assess the impact on sugar intakes from consuming formulated beverages.

The Decision

On the basis of public health and safety, informed consumer choice and having regard to Ministerial policy guidance, minimum effective regulation, best scientific evidence available, the promotion of fair trading and the desirability of an efficient and competitive food industry, FSANZ is recommending the following regulatory approach for formulated beverages:

- classification of formulated beverages as a general-purpose food;

- inclusion of a definition for formulated beverages in the Code, in association with compositional requirements that permit up to 24% fruit ingredients and total sugar content of 7.5 g/100 ml;

- application of generic labelling requirements to formulated beverages;

- permissions for the range of food additives requested by the Applicant (as detailed in Attachment 9); and

- permissions for the addition of 16 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
Beta-carotene	200 μg
Thiamin	0.28 mg
Riboflavin	0.43 mg
Niacin	2.5 mg
Folate	50 μg folic acid
Vitamin B_6	0.4 mg pyridoxine
Vitamin B_{12}	0.5 μg
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
Pantothenic Acid	1.3 mg
Calcium	200 mg
Iodine	38 μg
Iron	3 mg
Magnesium	80 mg
Selenium	17.5 μg (inorganic and organic forms)

Statement of Reasons

FSANZ has undertaken an assessment, using the best evidence available, of the draft variations to the Code (Attachment 1), incorporating defined vitamin and mineral permissions, specific compositional requirements, and a definition for formulated beverages, and considers that these draft variations should be approved for the following reasons:

- the regulation of formulated beverages provides assurance for consumers regarding the protection of public health and safety by;

    - permitting the safe addition of vitamins and minerals to formulated beverages;
    - permitting the addition of vitamins and minerals to formulated beverages where an inadequacy or deficiency exists; and
    - setting a compositional requirement on the total sugar content of formulated beverages;

- regulation of formulated beverages ensures certainty for industry balanced against the need to provide informed 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 COAG principles, and are therefore consistent with Ministerial policy guidance on voluntary fortification.

- the permitted range of vitamins and minerals is consistent with the principles of minimum effective regulation, the desirability of an internationally competitive food industry 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 formulated beverages in the Code promotes equity by providing a regulation which enables the manufacture of formulated beverages in Australia;
- the explicit recognition of formulated beverages 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 net benefits of permitting formulated beverages outweigh any potential costs to affected parties.

1. Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from the Australian Beverages Council Limited[10] on 26 June 2002 requesting the development of a new standard in the Code for formulated beverages.

Formulated beverages are described as non-alcoholic, water-based, flavoured beverages containing claimable amounts 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, compared with the request from the Applicant for 16 vitamins and minerals[11]. 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 Final Assessment Report discusses issues, including those raised in submissions, regarding the regulation of formulated beverages and recommends variations to the Code to permit the addition of specific vitamins and minerals to formulated beverages (Attachment 1).

1.1 Nature of Application

There have been a number of amendments made to this Application since its lodgement. A detailed summary of these amendments is at Attachment 2.

Since Draft Assessment, the Applicant has requested exclusion of cordials from the scope of the Application. In addition, the requested number of vitamin and minerals permissions has been reduced from the originally requested 23 to 16.

Therefore, the Applicant is now seeking permissions for formulated beverages as follows:

- 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;

Vitamin / Mineral	Maximum Claimable Amount Per 600 ml Reference Quantity
Beta-carotene	200 μg
Thiamin	0.28 mg
Riboflavin	0.43 mg
Niacin	2.5 mg
Folate	50 μg folic acid
Vitamin B_6	0.4 mg pyridoxine
Vitamin B_{12}	0.5 μg
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
Pantothenic Acid	1.3 mg

[10] Formerly known as the Australasian Soft Drink Association Limited.

[11] The Applicant is seeking permissions for a range of added vitamins and minerals (16) however based on the current market product profile it is unlikely that all permissions would be used in a single product.

Vitamin / Mineral	Maximum Claimable Amount Per 600 ml Reference Quantity
Calcium	200 mg
Iodine	38 µg
Iron	3 mg
Magnesium	80 mg
Selenium	17.5 µg (inorganic and organic forms)

- sugar at unspecified amounts;
- fruit juice, purée concentrates, orange peel extract and/or comminuted fruit; and
- a range of food additives (57 in total) currently permitted in the Code, excluding caffeine and carbon dioxide.

1.1.1 Basis of the Application

The Applicant requested the creation of a standard for formulated beverages, as a general-purpose food, partly as a means of addressing the purported disadvantage that Australian beverage manufacturers are experiencing with the importation of formulated beverages from New Zealand under the *Trans-Tasman Mutual Recognition Arrangement* (TTMRA). The Applicant also cited consumer demand for formulated beverages as underpinning the basis of their request.

2. Regulatory Problem

Currently there are no specific provisions in the Code for the addition of vitamins and minerals to formulated beverages. 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 formulated beverages from over-exposure to some vitamins and minerals and from increased sugar intake. Consumers would be unaware of any potential risks associated with the consumption of formulated beverages. Hence an assessment of formulated beverages is essential to protect public health and safety.

In addition, Australian beverage manufacturers are currently unable to manufacture formulated beverages, unless they utilise Standard 2.9.4 - Supplementary Sports Foods Standard (Sports Foods Standard). This is inconsistent with the intent of the Sports Foods 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)[12]. New Zealand manufacturers are able to produce formulated beverages 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.

[12] http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_regs

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. FSANZ will on a case-by-case basis, balance these matters and assign them appropriate weightings, when assessing a particular application or proposal. In compliance with administrative law requirements, FSANZ does not inflexibly apply policy guidelines as this would result in a failure to give due and proper consideration to the other four matters.

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

- protect the public health and safety of consumers of formulated beverages;
- enable consumers to make informed choices about formulated beverages; and
- ensure a regulatory system which promotes efficiency and competitiveness for all sections of the formulated beverages industry.

4. Background

4.1 Regulatory Framework

4.1.1 Australia and New Zealand

In Australia, foods are regulated under the Code and therapeutic goods are regulated under the Commonwealth *Therapeutic Goods Act 1989*. Whilst in New Zealand[13], 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 supplements'[14] under the NZDSR.

4.1.1.1 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. Details of the permissions for vitamins and minerals contained in the NZDSR are outlined in Attachment 11.

In Australia, these 'dietary supplements' could be regarded as foods i.e. food-type dietary supplements [15] or medicines/therapeutic products depending on the nature of the product.

Advice from the New Zealand Government[16] 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 Government[17] 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 Government[17] has foreshadowed changes to the NZDSR including 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.

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

[14] 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*.

[15] The term food-type dietary supplement 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'.

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

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

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* establishing a framework for the harmonisation of food standards in Australia and New Zealand, underpinned by a single set of food regulations in both countries.

4.1.2 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.

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 whether they comply with the Code or not.

4.1.3 Joint Australia and New Zealand Therapeutic Goods Agency

Australia and New Zealand are in the process of establishing a bi-national agency that will jointly 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 food-type dietary supplements will be regulated by the Code.

4.1.4 International regulations

4.1.4.1 Codex Alimentarius

Codex has no specific texts that address formulated beverages 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 formulated beverages. Although formulated beverages 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.

Despite a growing global market, no overseas regulation pertaining specifically to formulated beverages has been identified. However, 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 formulated beverages, both Canada and the United States have respectively proposed or extant policies in relation to fortification. A review of the Health Canada policy[18] 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 Administration[19] does not encourage the indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugar; or snack foods such as candies and carbonated beverages. To preserve a balance of nutrients in the diet, manufacturers who elect to fortify foods are urged to utilise these principles when adding nutrients to food.

Similarly, the European Commission (EC)[20,21] proposes to prohibit the addition of vitamins and minerals in certain foodstuffs such as alcohol and unprocessed food including fruits, vegetables, meat, poultry and 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.

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*[22] (Policy Guideline). The Policy Guideline includes 'High Order' Policy Principles, separate 'Specific Order' Policy Principles and 'Additional Policy Guidance' for both mandatory and voluntary fortification.

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[18] Health Canada (2005) *Addition of Vitamins and Minerals to Foods 2005 – Health Canada's Proposed Policy and Implementation Plans*

[19] 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).

[20] 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

[21] Position of the Commission of the European Communities as at June 2005 on the *Proposal for a Regulation of the European Parliament And Council on The Addition of Vitamins and Minerals and of Certain other Substances to Foods.*

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

The 'High Order' Policy Principles restate the objectives of the FSANZ Act and include the COAG principle of minimum effective regulation. They take precedence over the policy guidance specifically provided on voluntary fortification.

In response to the Policy Guideline, FSANZ has developed a *Fortification Implementation Framework*[23]. This Framework is primarily an internal document, which details FSANZ's decision making, in light of the Policy Guideline, on the addition of vitamins and minerals to food. The Framework provides the context for standards development particularly as it relates to FSANZ's statutory obligations. It should be noted that the Framework will be updated as new or additional information comes to light.

4.2.2 Nutrition, health and related claims

In December 2003, the Ministerial Council referred a *Policy Guideline on Nutrition, Health and Related Claims*[24] 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 the development of the health claims Standard. However, health claims in relation to fortified foods including formulated beverages, do fall within the regulatory framework for nutrition, health and related claims. Therefore formulated beverages 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

The Ministerial Council has 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 Secretariat[25]. This Application is not seeking permissions for the addition of 'substances other than vitamin and minerals' to formulated beverages.

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 formulated beverages.

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[23] The Fortification Implementation Framework (May 2005) is available at www.foodstandards.gov.au

[24] 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>

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

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;

- 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. 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. beta-carotene), 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 fruit-based 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 per reference quantity.

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 specific labelling requirements.

Other pertinent Standards in Chapter 2 that merit consideration include:

- Standard 2.6.4 – Formulated Caffeinated Beverages, which allows for the addition of certain vitamins and minerals to 'energy drinks' and details specific labelling requirements; and

- Standard 2.9.4 – Formulated Supplementary Sports Foods (Sports Foods), 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. Sports foods 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, formulated beverages were considered within the scope of Proposal P235 – Review of 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. Food-type dietary supplements 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.

Work on this Proposal has been deferred pending development of policy guidance on the addition of substances other than vitamins and minerals. The adoption of policy guidance on the addition of vitamins and minerals to food provides a framework to progress this Application independently of the review of food-type dietary supplements.

4.4.2 Application A424 – Fortification of Calcium to Foods

In September 2005, FSANZ re-affirmed its decision to permit the voluntary addition of calcium to fruit- and vegetable juices and drinks, soups and savoury biscuits as outlined in the Second Review of Application A424 – Fortification of Foods with Calcium. At the October 2005 meeting, the Ministerial Council endorsed the findings of the review thus permitting the addition of calcium to the requested foods. The Council also endorsed a package of measures to review the impact of this and future voluntary fortification permissions (refer to Section 10 Implementation and Review).

4.5 Formulated Beverage Market and Product Range

4.5.1. International

Formulated beverages 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 'sugary' beverages that may be perceived as 'nutritionally inferior' towards healthier alternatives. This 'wellness' shift shows consumers are looking towards a healthier lifestyle and are applying criteria such as 'Is it healthy?, Is it good for me?' to determine what to eat and drink. It is reflected by an increase in the proportion of 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 day[26,27,28].

[26] *It's about health, convenience, value for money and image*. Bill Sanderson, Retail World, Volume 58 No. 6, April 2005.
[27] *Times and Trends: A snapshot of trends shaping the CPG industry*, Grocery Manufacturers of America, December 2004.
[28] Commercial-in-confidence industry data.

Sales of formulated beverages, 'energy drinks' and other 'fortified' beverages in the United States, 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 2007[29]. The majority of this growth has been attributed to 'energy drinks' and vitamin-enhanced beverages.

Formulated beverage 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% per year over the next five years[30]. Notwithstanding this decline in growth, the formulated beverage category is seen as 'relatively underdeveloped' with capacity for continuing expansion[20]. Formulated beverages 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 matured[20]. Based on current market trend data[31] showing consumers want products that are healthy, convenient and good value for money, there appears to be potential for market growth of formulated beverages.

Internationally, the formulated beverage 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 formulated beverage 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.

4.5.2 Australia and New Zealand formulated beverages market

In June 2003, FSANZ commissioned surveys in both Australia and New Zealand to assist in the assessment of this Application and Proposal P235 – Review of Food-Type Dietary Supplements. The objectives were two-fold. Firstly, to identify those products available which are consumed as food but are marketed or formulated as food-type dietary supplements; and secondly, to examine the food-type dietary supplements industry focusing on structure and market share. For both countries, beverages comprised the largest category. More recently (March/April 2005), FSANZ staff conducted supermarket surveys to determine the current formulated beverage product range in both Australia and New Zealand. Note, these surveys were not exhaustive and may not reflect all available formulated beverage products. Using the results from the 2003 Food-type Dietary Supplements 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 2005 Formulated Beverages Supermarket Surveys including specific details on the current product range in Australia and New Zealand is at Attachment 4. This information has assisted to provide a picture of changes over time in the formulated beverage market in New Zealand and Australia.

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[29] *An Australasian Standard for Formulated Water-Based Non-Alcoholic (Functional) Beverages – The Economic Benefits*. The Allen Consulting Group, July 2002.
[30] *Functional Soft Drinks – An International Perspective*. Leatherhead Food International, November 2003.
[31] *What's Hot Around the Globe*, AC Neilsen Global Services, December 2004 – used in the Retail World article.

4.5.2.1 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 million[32].

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 formulated beverages 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 Australia[33].

The 2005 Formulated Beverage Surveys identified ten products, compared with nine in the 2003 Food-type Dietary Supplements surveys. 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.

4.5.2.2 Australia

The market for formulated beverage-type products in Australia is relatively small but is experiencing growth.

Unlike New Zealand, the Australian market has changed somewhat since 2003. In the 2003 Australian Food-type Dietary Supplements Surveys, only three products were identified that would be classified as formulated beverages. All three products were imported from New Zealand via the TTMRA. In the 2005 Formulated Beverages Supermarket Surveys the product range had significantly increased to 20. Of these, only four were being imported from New Zealand. The remaining products were either being manufactured under the Sports Foods Standard or appear to be non-compliant with the Code. Whilst the composition of the products manufactured and labelled as 'formulated supplementary sports foods' include some of the vitamin and mineral permissions permitted, manufacturers do not utilise the amino acid and other ingredients permissions in this standard.

The market for formulated beverage-type products manufactured under the Sports Foods Standards is valued at approximately $A10 million for 2004 (*personal communication* Tony Gentile 2005). Whilst some local companies have produced niche products 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 these beverages.

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

[33] *Statistics New Zealand – Overseas trade exports for calendar years 1995-2004*. Reference number JOA7632.

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.

Structurally, the Australian 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 products. 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.

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

4.6 Consumer Research on Food-Type Dietary Supplements

In June 2003, FSANZ commissioned qualitative consumer research in both Australia and New Zealand to assist future decision-making on issues related to food-type dietary supplements including this Application. Specifically, the purpose of the research was to examine consumers' awareness, familiarity, understanding and use of food-type dietary supplements 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.

The key findings of this research included:

a low awareness and use of food-type dietary supplements;
a preference for labelling to distinguish between natural and added nutrients;
little support for additional labelling elements such as advisory statements; and
the need to inform and educate consumers of the labelling of food-type dietary supplements to ensure consumers can make informed choices.

A summary of the research findings is provided at Attachment 12. A copy of the full report *A qualitative consumer study related to food-type dietary supplement labelling* is available on the FSANZ website[34].

5. Relevant Issues

5.1 Risk Assessment

A risk assessment has been conducted to determine the nutrition and safety risks arising from the requested addition of vitamins, minerals and food additives to formulated beverages. The Applicant has requested (following amendments) the addition of 16 vitamins and minerals up to a level of 25 % RDI per 600 ml (reference quantity) with the exception of vitamin C at 100% RDI per 600 ml, extensions to the permissions for 57 additives, and the addition of sugar.

[34] http://www.foodstandards.gov.au/mediareleasespublications/publications/consumerstudyrelatedtofoodtypedietarysupplementlabellingjuly2003/

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 formulated beverages.

A nutrition assessment has been undertaken to assess the potential nutritional need and health benefit in support of vitamin and mineral additions to formulated beverages. 'Nutritional need and health benefits' encompasses two concepts: i) nutritional need, referring to inadequate intakes or deficiency states; or ii) 'health benefits', referring to potential benefits, other than meeting nutritional need. In addition, the nutrition assessment has also assessed the potential for an increase in sugar intakes of the population from formulated beverages consumption, and any subsequent risks to population health, as well as considering the risks from any increase in the consumption of acidified beverages. A detailed report is provided in **Attachment 5 – Nutrition Assessment** and is summarised below.

The potential for formulated beverages 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 – Micronutrients**[35], and is summarised below.

The methodology used for dietary modelling of the vitamins and minerals is described in **Attachment 7 – Dietary Modelling Methodologies for Micronutrient Intake Assessment**. A primary data source for the dietary modelling is the 1995 Australian and the 1997 New Zealand National Nutrition Surveys (NNS). It is recognised that limitations exist within the NNS data, which relate to the age of the data and the changes in eating patterns that may have occurred since the data were collected. These limitations have been factored into the considerations of results obtained from the dietary modelling.

The potential for health risks associated with the use of the food additives in formulated beverages has also been examined. A detailed report that examines the nature of any potential hazard, an estimate of the dietary exposure from the substitution of formulated beverages 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 nutritional need and health benefit for adding the requested vitamins and minerals to formulated beverages, and to examine other nutrition-related health risks to the broader Australian and New Zealand populations. The overarching approach to the Nutrition Assessment has been to consider these issues in the context of FSANZ's statutory objectives, including having regard to Ministerial policy guidance.

[35] For the purpose of this report the term 'micronutrient' is used for vitamins and minerals

5.1.1.1 Nutritional need and health benefit

The Policy Guideline supports 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 'nutritional need and health benefit', the first step was to determine if there is a nutritional need, by assessing the extent of existing deficiency or inadequacy of vitamin and mineral intakes within Australia and New Zealand.

If either inadequacy or deficiency was identified, then the 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 an increase in the intake of a vitamin and/or mineral 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 'nutritional need and health benefit'.

The results of the assessment of the nutritional need and health benefit for each of the requested vitamins and minerals are illustrated in Figure 1 below. In this figure, group 1 refers to those vitamins and minerals that were identified as having a nutritional need, and group 2 to those without. In all cases where a nutritional need based on inadequacy was identified, this included the young adult segment of the population (i.e. 20-39 years), who appear to be the major target group for these beverages.

Figure 1: Assessment of Nutritional need and Health benefit

<table>
<tr><th colspan="2">Vitamin / Mineral</th><th>Nutritional Need</th><th colspan="2">Health Benefit[3]</th><th>Existence of a Nutritional need and or Health benefit</th></tr>
<tr><td>Group 1</td><td>Riboflavin
Folate
Vitamin B_6
Vitamin D
Vitamin E
Calcium
Iodine
Iron
Magnesium
Selenium</td><td>Evidence of inadequacy[1] > 3% of population intakes were below the EAR,

OR

Evidence of deficiency existed[2]</td><td colspan="2"></td><td>Identified as having a nutritional need and/or health benefit</td></tr>
<tr><td rowspan="2">Group 2</td><td>Thiamin
Niacin
Vitamin B_{12}
Vitamin C</td><td>< 3% of population had intakes below the EAR,
AND
No evidence of deficiency</td><td rowspan="2">Assessed for the potential to deliver a health benefit

(None met FSANZ criteria for a 'health benefit')</td><td rowspan="2"></td><td rowspan="2">No nutritional need and/or health benefit identified</td></tr>
<tr><td>Beta-carotene
Pantothenic acid</td><td>Unable to assess for inadequacy (no EAR)
AND,
No evidence of deficiency</td></tr>
</table>

See over page for figure legends.

Legend to Figure 1 above:

1. 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). 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.
2. 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.
3. 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.

Therefore the vitamins and minerals in Group 1 (Figure 1) met all criteria for demonstration of a nutritional need and/or health benefit in support of their addition to formulated beverages. These are as follows:

Vitamins	Minerals
Riboflavin	Calcium
Folate	Iodine
Vitamin B_6	Iron
Vitamin D	Magnesium
Vitamin E	Selenium

The vitamins and minerals of Group 2 (Figure 1) did not demonstrate a nutritional need and / or health benefit in support of their addition to formulated beverages.

5.1.1.2 Nutrition-related health risks

In addition to assessments on nutritional need and health benefit, the Nutrition Assessment has identified the sugar content and acidity of formulated beverages as potential nutrition-related health risks. In order to assess the health risks associated with the consumption of formulated beverages, FSANZ has undertaken a process to first identify the nature and severity of the risks associated with sugar content and acidity of beverages generally, and then to determine whether such risks will increase following the introduction of formulated beverages. This process is outlined below, first for the sugar content of beverages in relation to overweight/obesity and dental caries, and second for beverage acidity and dental erosion.

'Sugar-containing beverages' are referred to in the scientific literature as including standard carbonated beverages, fruit juices and drinks, and cordials; but not milk-based beverages (Appendix 9 to Attachment 5). The content of total sugar from natural and added sources in the beverages considered in the literature therefore ranged between about 5-15 g /100 ml. The Nutrition Assessment report adopted the term 'sugar-containing beverage' to reflect the above definition of water-based beverages in the literature.

While conducting the assessment on sugar intakes and acidic beverages, FSANZ received comments from the Applicant, detailing ten separate articles critical of an association between sugar-containing beverage intakes and overweight/obesity. Of the ten articles provided by the Applicant, only four were considered suitable when compared to criteria used for the assessment (see Attachment 5 for more details). FSANZ had the assessment peer-reviewed to further ensure that the available evidence was considered in an objective manner.

Following assessment of the available literature, and subsequent peer-review, it was determined that an increase in sugar-containing beverage intakes was a risk factor for overweight and obesity. It was also determined that the sugar content of beverages represents a significant risk to dental health due to the positive association between sugar-containing beverage intake and dental caries. Therefore, a risk to public health could develop if the introduction of a formulated beverage category significantly increased population intakes of total sugar.

To assess whether these risks from consuming sugar-containing beverages were likely to arise in the Australian and New Zealand diets, FSANZ undertook dietary modelling at Final Assessment to determine if the consumption of sugar would change significantly with the introduction of formulated beverages.

The results of the modelling on sugar intakes show that the total substitution of all sugar-containing beverages by a formulated beverage category with an unweighted mean total sugar content of 5.5 g / 100 ml (reflecting the mean of the current market) produces very little change in per capita total sugar intake. Only if all formulated beverages contained 7.5 g/ 100 ml (proposed maximum total sugar level) under the conservative condition of complete substitution of sugar-containing beverages would per capita total sugar intake modestly increase.

On the basis of these findings it was concluded that although sugar-containing beverages were identified as a risk factor for overweight and obesity, and dental health, it is unlikely that this potential risk will translate into actual adverse public health outcomes in relation to sugar intake and obesity, or in relation to sugar intake and dental caries with the introduction of formulated beverages.

The acidity of beverages was also assessed, and it is concluded that the consumption of acidic soft drinks and like beverages is probably associated with dental erosion. However, exacerbation of current rates of dental erosion would occur only if there was a net increase in acidified non-alcoholic beverage consumption rather than substitution of the currently available products. Since water-type formulated beverage products are more likely to be acidified than their plain bottled water counterparts (which make up a 10% share of the 2005 beverage market), their consumption instead of these more neutral bottled waters may result in a net increase in acid beverages consumed and therefore pose a potential risk of increasing occurrence of dental erosion.

5.1.1.3 Bioavailability

Several techniques have been developed to assess bioavailability ranging from *in vitro* methods to human balance studies and studies of impact on target body systems. However, controlled studies of fasting consumption of a single food examining the absorption or metabolic utilisation of nutrients are unlikely to provide an accurate assessment of the uptake and regulation within the body. This is because of different meal effects and the range of host-related modifiers that can vary gastrointestinal absorption in response to the internal environment.

Comparison of gastrointestinal absorption rates among vitamins and minerals – irrespective of whether naturally occurring or supplemental – shows wide variability with very few attaining complete intestinal absorption, and demonstrates that vitamins and minerals are not generally fully bioavailable.

FSANZ is unaware of any studies that have investigated the bioavailability of vitamins and minerals from formulated beverages. Because the bioavailability of any one vitamin or mineral is likely to be variable, and dependent on several factors, it is therefore not possible to draw conclusions on the actual bioavailability of vitamins and minerals either naturally occurring or added to individual foods, including those in formulated beverages.

5.1.2 Risk Assessment – Micronutrients

For the following vitamins and minerals, addition to formulated beverages at a level of 25% RDI / 600 ml (100% RDI per 600 ml for vitamin C) raises 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, and selenium.

However for iron and iodine, the addition to formulated beverages at a level of 25% RDI/600 ml does not raise any public health and safety concerns for the general population, yet there may be a risk for certain sectors of the population:

Iodine: Individuals with thyroid disorders or a long history of iodine deficiency may respond adversely to iodine in formulated beverages at a level of 37.5 μg per 600 ml.

Iron: 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 formulated beverages at a level of 3 mg per 600 ml serve may be a concern to these individuals.

Currently there are no forms permitted in Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions for pantothenic acid and selenium. The requested permitted forms for pantothenic acid 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 formulated beverages. All of these food additives are currently permitted in Standard 1.3.1 – Food Additives.

FSANZ has not performed an independent hazard identification and characterisation of the 57 food additives, and instead relied upon the assessment reports from the Joint FAO/WHO Expert Committee on Food Additives (JECFA). JECFA has established numerical Acceptable Daily Intakes (ADI)[36] for some, and established an ADI 'not specified'[37] for many in this group.

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[36] 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*

[37] 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.*

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, even if there would be an increase in exposure resulting from their use in formulated beverages.

For the additives with a numerical ADI, dietary exposure assessments were conducted. The risk characterisation concluded that the addition of the following food additives to formulated beverages at the requested concentration would not result in an increase in exposure, and therefore 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 isobutrate, glycerol ester of wood rosin, and dioctyl sodium succinate.

The addition of the following food additives to formulated beverages at the requested concentration could result in a small increase in exposure, however it would not pose a public health and safety risk: annatto, benzoates, acesulphame potassium (ace K), saccharin and alitame.

5.1.4 Risk assessment conclusions

5.1.4.1 Vitamins and minerals

The Tables summarise the findings of the nutrition assessment and the risk assessment in relation to the addition of vitamins (Table 1) and minerals (Table 2) to formulated beverages.

The vitamins and minerals that met all criteria for demonstration of a nutritional need and health benefit are marked with a tick in the column *Meet Criteria Nutrition Assessment* of Table 1 and 2. The vitamins and minerals that did not raise public health and safety concerns when added to formulated beverages at a level of 25% of the RDI/600 ml (100% RDI/600 ml for vitamin C) are marked with a tick in the column '*Meet Criteria Risk Assessment'* of Table 1 and 2.

Table 1: Risk Assessment conclusions on the requested vitamin additions

Vitamins	**Meet Criteria Nutrition Assessment**	**Meet Criteria Risk Assessment**	**Eligibility for Addition to Formulated Beverages (Combined outcomes of the Nutrition Assessment and Risk Assessment)**
Beta-carotene		✓	
Thiamin		✓	
Riboflavin	✓	✓	✓
Niacin		✓	
Folate	✓	✓	✓
Vitamin B_6	✓	✓	✓
Vitamin B_{12}		✓	
Vitamin C		✓	
Vitamin D	✓	✓	✓
Vitamin E	✓	✓	✓
Pantothenic acid		✓	

Table 2: Risk assessment conclusions on the requested mineral additions

Minerals	Meet Criteria Nutrition Assessment	Meet Criteria Risk Assessment	Eligibility for Addition to Formulated Beverages (Combined outcomes of the Nutrition Assessment and Risk Assessment)
Calcium	✓	✓	✓
Iodine*	✓	✓	✓
Iron*	✓	✓	✓
Magnesium	✓	✓	✓
Selenium	✓	✓	✓

* 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.

In conclusion, the following vitamins and minerals met both the nutrition and risk assessment criteria: riboflavin, folate, vitamin B_6, vitamin D, vitamin E, calcium, iodine, iron, magnesium and selenium. While beta-carotene, thiamin, niacin, vitamin B_{12}, vitamin C, and pantothenic acid do not raise public health and safety risks, they do not meet the nutrition assessment criteria.

As the actual bioavailability of any one vitamin or mineral is dependant on a wide range of factors, it is not possible to draw definite conclusions on the bioavailability as it applies to any individual food product, including formulated beverages. It is, however, expected that the vitamins and minerals in formulated beverages are bioavailable to varying extents.

5.1.4.3 Sugar content and acidity of formulated beverages

A potential risk was identified between sugar-containing beverage intakes and overweight/obesity and dental caries, and between consumption of acidified beverages and dental erosion.
However, the impact depends on the pattern and level of substitution of this product group, and the range of products available. Results of the dietary modelling indicate that the introduction of formulated beverages into the market is unlikely to further adversely affect public health in relation to sugar intake and obesity, or in relation to sugar intake and dental caries. This is also the case generally in relation to acidified beverages and dental erosion. However, because water-type formulated beverages are more commonly acidified than bottled waters, substitution of bottled water by formulated beverages may increase the risk of dental erosion.

5.1.4.4 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 formulated beverages 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 the recommended approach to managing the identified public health and safety risks associated with formulated beverages, other broader issues relevant to the regulation of formulated beverages, and considers and responds to issues raised in submissions.

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 formulated beverages 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 formulated beverages product.

The Applicant has indicated that the marketing of formulated beverages was, on the evidence of products available at the time, aimed at adults, showing formulated beverages to be more interesting tasting beverages which contain low levels of vitamins and minerals. Industry research[38] reports that quenching thirst is a key reason for selecting formulated beverages for both men and women. Women consumers of formulated beverages are also seeking more energy and health, where men tend to be more likely to seek re-hydration from these products. Further, the premium pricing of the products, seeking a higher margin than the traditional carbonated soft drink market, would act as a disincentive for the potential younger consumer.

Market intelligence suggests the drivers for formulated beverages would be their appeal to young adults 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[39].

However, an incidental target group for formulated beverages appears to be children and teenagers. Whilst the Applicant has advised formulated beverages will not be targeted towards children, industry data on a leading brand of formulated beverages 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.

5.2.1.1 Conclusion

The identified target group for formulated beverages are adults aged 20-39 years old. However, noting evidence from current marketing practices as described above, it is appropriate that the recommended risk management strategies for formulated beverages include consideration of both target and incidental target groups i.e. children and teenagers.

[38] Commercial-in-confidence industry data.

[39] The Allen Consulting Group, Report to the Australasian Soft Drink Association, *An Australasian Standard for Formulated Water-Based Non-Alcoholic Beverages: The Economic Benefits*, July 2002.

5.2.2 Characterising the product category of formulated beverages

5.2.2.1 Formulated Beverages as General-Purpose Foods

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

Currently the Code distinguishes two broad categories of purpose:

- General-purpose food i.e. food that is widely available for consumption by the general community (the vast majority of foods); and

- Special-purpose food i.e. food that is specially produced to satisfy particular dietary requirements that exist because of a particular physical or physiological need, and/or specific diseases and disorders and which are presented as such. Part 2.9 of the Code contains the standards for special-purpose food e.g. infant formula and foods, formulated meal replacements and sports foods.

The above description of special purpose food reflects the Codex definition of foods for special dietary uses[40]. In this case, the phrase particular dietary requirements refers to nutritional requirements that cannot be met by consumption of a normal (solid) diet. Physical and physiological need includes reference to normal states in the life cycle such as pregnancy and lactation, as well as physical (including lifestyle) and physiological conditions that occasion the use of special purpose food. This description not only acknowledges the nature of special purpose foods but also an underpinning regulatory principle that considers not only the primary objective of safety but also efficacy in meeting the nutritional needs (i.e. adequacy) of certain at-risk individuals.

The likely target group for formulated beverages do not have 'particular dietary requirements'. In addition, the anticipated presentation and marketing of these products will be as general-purpose foods. Therefore, it is appropriate that the same approach, including regard for policy guidance, be applied to formulated beverages as for other fortified general-purpose foods. Furthermore, the Application is seeking vitamin and mineral additions at amounts relatively comparable to permitted fortification levels for other general-purpose foods (i.e. 25% RDI with the exception of vitamin C, at 100% RDI, per a 600 ml reference quantity).

The Ministerial Council has recently requested that FSANZ undertake a review of Part 2.9 of the Code to ensure that only foods that are prepared to satisfy the particular dietary requirements of nutritionally at-risk groups fall within this category, and not foods that will, as a matter of course, be promoted and consumed as a general food.

Therefore as formulated beverages do not fall within the category of special purpose foods, it is appropriate that they be regulated as general-purpose food.

[40] Section 2.1 Codex General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses, CODEX STAN 146-1985.

5.2.2.2 Definition

The need to clearly define formulated beverages is a key issue in the regulation of formulated beverages to ensure that the product category of formulated beverages is unambiguously described and does not inadvertently act as a means to circumvent other, more appropriate food standards. Definitions for regulatory purposes usually include reference to elements of composition and/or purpose. As formulated beverages are considered general-purpose food, composition therefore represents the most suitable defining feature for formulated beverages.

The Applicant has provided information on the likely range of products that may be produced as formulated beverages. 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; and
- unsweetened, flavoured, still fruit drinks and fruit juice drinks with juice added as an ingredient.

'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*.

Given the proposed composition of formulated beverages as described by the Applicant above, formulated beverages can be considered a sub-category of water-based beverages, which may or may not include fruit ingredients.

Therefore, FSANZ is recommending the following definition for inclusion in Standard 2.6.2:

> *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:*
>
> - *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*
> - *sugars.*

This definition reflects the range of ingredients and likely composition of formulated beverages 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.

It should also be noted that implicit to this definition is that formulated beverages are 'ready-to-drink' and do not include concentrates or drink bases. To minimise any possible confusion, an editorial note will also be included in the Standard which states:

> *Formulated beverages are liquid products which are sold in a form designed to be consumed as is, that is, without the need to reconstitute or add further ingredients.*

5.2.2.3 Compositional criteria for formulated beverages

5.2.2.3.1 Fruit ingredients

The above definition although considered explicit in terms of compositional description does not necessarily distinguish formulated beverages from other water-based beverages currently regulated in the Code. As previously discussed, it is important that formulated beverages are unambiguously described and do not inadvertently act as a means to circumvent other, more appropriate food standards.

For instance, there is a direct compositional overlap of formulated beverages with other beverages such as fruit drinks. The definition of a 'fruit drink'[41] in the Code includes the same range of ingredients as formulated beverages. In addition, the Code prescribes a minimum amount of fruit[42] that must be present in a fruit drink.

Formulated beverages can be considered a sub-category of water-based beverages, which may or may not include fruit ingredients, and by definition contain added vitamins and minerals. Fruit drinks on the other hand, also represent a broad category of water-based beverages that must include fruit ingredients, but do not necessarily contain added vitamins and minerals.

Given the similarity of ingredients, the primary difference between formulated beverages and fruit drinks therefore lies in the fortification permissions available to each product category.

Currently only fruit juices and fruit drinks containing at least 25% fruit ingredients are permitted to contain a small number of added vitamins (i.e. folate, vitamin C and carotene forms of vitamin A) in Standard 1.3.2 according to the modified restoration[43] principle. The proposed permissions for formulated beverages include these vitamins. Consequently permitting the addition of a wider range of vitamins and minerals to formulated beverages could provide an avenue for fruit drinks containing greater than 25% fruit ingredients access to broader fortification permissions. This could in effect render the current permissions for fruit juice drinks extraneous and create regulatory ambiguity for a large beverage category.

For this reason, it is considered necessary to apply a compositional criterion of equal to or less than 24% fruit ingredients so as to clearly distinguish formulated beverages from other fruit juice based products particularly in respect to vitamin and mineral permissions. Furthermore, as FSANZ is not proposing to require additional labelling specific to formulated beverages, a compositional criterion is appropriate and should assist product identification and regulatory clarity, particularly for enforcement agencies.

[41] Contained within Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drinks.
[42] The Code requires fruit drink to contain at least 5% (except in the case of passionfruit which requires 3.5%) specified fruit ingredients.
[43] The principle of modified restoration is described in the Fortification Policy Guideline.

The 2005 Formulated Beverages Supermarket Surveys indicated that currently available formulated beverages would meet this compositional criterion as the majority of products generally contain less than 5% fruit ingredients. Thus, the compositional criterion of no more than 24% fruit ingredients does to a certain extent provide for industry innovation.

5.2.2.3.2 Total sugar

Integral to the definition of formulated beverages is the addition of vitamins and minerals. The Applicant has indicated that these products will be marketed and positioned in such a way that highlights them as being 'healthier' alternatives to traditional water-based beverages, including soft drinks, to meet consumer demand. Market trend data indicates that consumers' today view hydration as a legitimate part of preventive health care with the addition of vitamins and minerals to bottled water, seen as inherently healthful[44,45].

In addition to the vitamin and mineral permissions, the range of permitted ingredients including fruit and sugar can also influence both the actual nutrient profile and the perceived 'healthiness' of formulated beverages.

Therefore it is appropriate to consider the permitted ingredients as defining elements of formulated beverages to ensure the integrity of the product range and to minimise any ambiguity with other categories of water-based beverages.

As formulated beverages are a sub-set of water-based beverages and as a compositional criterion has been applied to the fruit ingredients (as discussed above), 'sugars' are the only remaining ingredient that are a defining element. Thus FSANZ is applying a compositional criterion of sugar in formulated beverages.

Utilising a daily intake reference value for sugar of 90 g[46] and noting public health recommendations[47] which encourage moderate sugar intake, 50% of this reference value has been applied to the requested reference quantity of 600 ml to determine an appropriate compositional criterion. This equates to 45 g of sugar per 600 ml, or 7.5 g of sugar per 100 ml of formulated beverage.

From the 2005 Formulated Beverages Supermarket Surveys, FSANZ has identified three and four formulated beverages in Australia and New Zealand respectively that contain greater than 7.5 g sugar per 100 ml. Therefore the majority of currently available products meet this criterion and qualify as formulated beverages.

To assist manufacturers in producing commercially acceptable products and to facilitate product innovations, FSANZ has excluded formulated beverages from restrictions on the use of intense sweeteners (see Section 5.2.6.2).

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[44] Kimberly J Decker, *Wonder Waters: Fortified and Flavoured Waters*, Food Product Design August 2003
[45] Donna Berry, *In pursuit of wellness*, posted on 19 May 2004 at: http://www.dairyfoods.com/CDA/ArticleInformation/coverstory/BNPCoverStoryItem/0,6809,125291,00.html

[46] As per Subclause 7(3) of Standard 1.2.8 – Nutrition Information Requirements.
[47] National Health and Medical Research Council (2003) *Dietary Guidelines for Australian Adults*. Canberra. Ministry of Health (2003) *Food and Nutrition Guidelines for Healthy Adults: A background paper*. Wellington. Ministry of Health.

5.2.2.4 Conclusion

Formulated beverages are considered general-purpose foods and therefore to ensure that they are clearly distinguished from other water-based beverages, Standard 2.6.2 of the Code will be amended to include a definition and specific compositional criteria for fruit ingredients and total sugar.

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 nutritional appropriateness as a vehicle for voluntary fortification. Based on the formulated beverages definition above, the following beverage types could be used as potential vehicles for voluntary fortification:

- water ± sugar ± non-nutritive sweeteners; and
- fruit juice drinks ± sugar ± 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, the primary focus for assessing the appropriateness of the potential food vehicle for this Application is the impact of consumption of the above identified beverage types on sugar and energy intakes.

5.2.3.1 Dietary guidance on drinks and sugar intake

The Australian Dietary Guidelines[48] (including those for children and adolescents) encourage water as the preferred drink and recommend only moderate consumption of sugar and foods containing sugar including beverages. Other drinks considered of value include milk and milk alternatives such as fortified soy milk. Whilst fruit and vegetable juices are noted as adding variety and fluid intake to the diet, they are not considered obligatory, particularly if the recommended amounts of whole fruits and vegetables are consumed. Moderation is recommended in relation to consumption of soft drinks and cordials containing sugar because of the energy added to the diet without additional nutrient value. However, occasional use of low-joule drinks is recognised as bringing variety to the diet.

Similarly, New Zealand dietary guidelines[49] also recommend choosing food and drinks that are low in sugar to avoid excess energy intake. They encourage limiting the consumption of beverages such as fruit juices, cordials, energy and soft drinks due to their high sugar content.

[48] National Health and Medical Research Council (2003) *Dietary Guidelines for Australian Adults*. Canberra. National Health and Medical Research Council (2003) *Dietary Guidelines for Children and Adolescents*. Canberra.
[49] Ministry of Health (2003) *Food and Nutrition Guidelines for Healthy Adults: A background paper*. Wellington. Ministry of Health.

5.2.3.2 Total sugar and energy content of water-based beverages

The table below shows the total sugar and energy content for commonly consumed water-based beverages and formulated beverage-like products 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
Formulated beverages water, flavoured +/- added sugar‡	0.0 – 2.3	2-41
Formulated beverages 2-5% Fruit Juice‡	2.0 - 5.4	38 - 34
Formulated beverages > 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 most formulated beverages contain relatively low levels of sugar, products with higher sugar levels are possible within the present scope of the Applicant's request. As the table above shows, some formulated beverages currently contain sugar levels similar to amounts found in carbonated soft drinks, cordials and fruit juices and drinks. Consequently, if the addition of vitamins and minerals increases the nutritional attractiveness and thus marketability of formulated beverages, there is potential for consumers to be misled as to the nutritional attributes of these products, thereby adversely impacting on their nutritional health.

This could be inconsistent with policy guidance. Noting the application of a compositional criterion on total sugar, FSANZ has examined the appropriateness of formulated beverages within this parameter more fully below.

5.2.3.3 Serving size of formulated beverages

The serving sizes of formulated beverages are generally larger than the standard serving size for soft drinks, juices and cordials. Market intelligence[50] indicates that the intended purpose of formulated beverages 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 formulated beverages be 600 ml.

The availability of formulated beverages in larger serving sizes does however raise some concern if consumption of a greater volume of beverage leads to increased sugar and energy intakes.

It should be noted that the requested reference quantity does not necessarily reflect the potential range of serving sizes for formulated beverage products. For example, it is possible that formulated beverages will be available in smaller serving sizes (e.g. 250 ml).

[50] *What's Hot Around the Globe*, AC Neilsen Global Services, December 2004 – used in the Retail World article.

5.2.3.4 Patterns of consumption

The *Fortification Implementation Framework* identifies that the introduction of a newly fortified food or food category into the market can result in four possible scenarios. In this case for example formulated beverages might:

- substitute for similar water-based beverages **(substitution)**;
- displace other food or beverage product(s) **(displacement)**;
- be consumed in addition to usual food and beverage intake **(addition)**; and/or
- not be consumed **(avoidance)**.

FSANZ recognises there is limited available information on how consumers respond to fortified foods, including formulated beverages, and the impact on food selection preferences. However, information can be extrapolated from consumer research on beverages generally. For example, consumer research[51] has found that consumers view drinks differently and thus the drivers of consumption vary. Any shift in beverage selection is thus more likely to occur within a similar beverage category as opposed to a shift between different categories. For example, it is unlikely that consumers would replace beverages such as milk, which are perceived to have specific functional benefits for bones and tend to be used at specific times of the day, with fruit juice which is viewed as a 'nutrition booster' and is usually consumed in the morning.

The main 'usage driver' for consuming formulated beverages is likely to be hydration. This would also apply to the broader category of water-based beverages. Therefore, FSANZ has concluded, on the available evidence, that the introduction of formulated beverages will most likely result in consumers substituting formulated beverages for their unfortified counterparts – that is, for other water-based beverages. This is also supported by market trend data which highlights a 'wellness' shift away from traditional beverages to those which are 'healthier'. FSANZ is not aware of any evidence to suggest that consumers will displace foods for formulated beverages or consume formulated beverages in addition to other beverages.

5.2.3.5 Potential for formulated beverages to adversely impact on nutritional health

FSANZ's risk assessment concluded there would be a risk to public health if the introduction of a formulated beverage category significantly increased population intakes of total sugar. Analyses of the intake of total sugar, if formulated beverages are permitted in the marketplace, reveal that sugar intake is not expected to increase.

However, the extent of change in per capita total sugar intake depends on the level and pattern of substitution and the range formulated beverages available.

FSANZ has also considered the likely increase on consumption of acidified beverages and their possible impact on dental erosion if formulated beverages are permitted. The Nutrition Assessment has examined the evidence and found that there is a positive association of consumption of acidified soft drinks and like beverages with dental erosion. However, it is noted that dental erosion also depends on a number of other contributing factors.

[51] TNS Social Research (2005) *Analysis of Fortification of Foods with Calcium Research*. A research report commissioned by FSANZ.

Therefore, the risk from dental erosion associated with formulated beverages will depend, in part, on the types of products that are being replaced by formulated beverages and these other contributing factors.

5.2.3.6 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. 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.*

FSANZ's 2003 food-type dietary supplements consumer research investigated consumers' perceptions on the importance of the composition of the food vehicle (see Attachment 12). 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 the likelihood that they would be 'unfairly' persuaded to buy the products. Only a minority felt 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.

There is a potential risk that consumers could be misled as to the nutritional quality of formulated beverages. As previously discussed (see section 5.2.2.3.2), the addition of vitamins and minerals to formulated beverages is likely to enhance their nutritional attractiveness and subsequently consumers may perceive formulated beverages as 'healthier' beverage alternatives. As some currently available formulated beverage type products contain higher levels of sugar (up to 11.3 g per 100 ml), this may result in consumers being unaware that they are consuming greater amounts of sugar and energy which may be exacerbated by the larger serving sizes commonly used for formulated beverages.

However, the application of the compositional criterion for sugar lessens this risk. In addition, nutrition labelling and the proposed health claims framework will also assist consumers to make informed choices and reduce the likelihood that consumers will be misled.

5.2.3.7 Conclusion

In assessing the appropriateness of the food vehicle, FSANZ has examined the potential for formulated beverages to adversely impact on public health and safety. Specifically, FSANZ has assessed the issues identified in the nutrition assessment including the potential for formulated beverages to increase consumption of sugar and energy intakes, the serving size of formulated beverages, and likely consumption patterns of formulated beverages. In addition, FSANZ has considered the potential for the requested formulated beverages product range to mislead consumers as to the nutritional quality of the fortified food.

The application of a compositional criterion for sugar to these products is a defining feature and positions formulated beverages as being a 'healthier' beverage alternative when compared to traditional water-based beverages such as soft drinks.

The conclusion from the dietary modelling clearly indicates that the introduction of formulated beverages is unlikely to increase per capita total sugar intakes. This is consistent with policy guidance by:

- not promoting consumption patterns inconsistent with nutrition policy and guidelines;
- reducing the potential for formulated beverages to promote increased consumption of foods high in sugar; and
- minimising the likelihood that consumers who perceive formulated beverages as 'healthier' alternatives to traditional soft drinks will be mislead as to the nutritional quality of formulated beverages.

Given the less significant risk to public health associated with consumption of acidified beverages and noting that other factors can influence dental erosion, FSANZ does not consider risk management strategies are warranted in this case.

5.2.4 Vitamin and mineral additions

As formulated beverages are considered general-purpose foods, the Policy Guideline is directly relevant to decisions on the regulatory control of the vitamin and mineral additions to formulated beverages. As previously discussed (Section 4.2.1) the Policy Guideline consists of 'High Order' Policy Principles that are FSANZ's statutory objectives, which take precedence over the 'Specific Order' Policy Principles for voluntary fortification.

5.2.4.1 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 formulated beverages and is the primary objective of the FSANZ Act. In addition, public health and safety underpins the Policy Guideline which provides guidance in relation to the need for fortification as well as assuring safety of any potential fortification. In assessing public health and safety, FSANZ adopts a comprehensive risk analysis process which systematically identifies, and determines the most appropriate options for managing, any risks using the best available scientific evidence.

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 this Application 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 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 'nutrition and health need' and safety determined that the following vitamins and minerals can be permitted for addition to formulated beverages 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

However, the risk assessment also identified that certain sensitive subpopulation groups may be at increased risk from the addition of iodine and iron to formulated beverages.

In the case of iodine, the risk assessment indicates that the addition of iodine to formulated beverages 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 formulated beverages will be labelled. Furthermore FSANZ is currently considering the mandatory fortification of food with iodine (Proposal P230) and consequently this issue will be further investigated as part of this Proposal.

Similarly, FSANZ's risk assessment identified that the addition of iron to formulated beverages poses no appreciable risk to public health and safety for the general population. However, individuals[52] 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 iron-rich 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 formulated beverages 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[53,54,55].

On this basis, FSANZ considers the potential health gain from permitting the addition of iron to formulated beverages 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, additional risk management strategies in relation to the addition of iodine or iron to formulated beverages are not considered necessary.

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[52] Up to 0.5% of the Caucasian population.
[53] National Health and Medical Research Council (2003) *Dietary Guidelines for Australian Adults*.
[54] New Zealand Ministry of Health (1998) *Food and Nutrition Guidelines for Healthy Adolescents: A background paper*.
[55] New Zealand Ministry of Health (2003) *Food and Nutrition Guidelines for Healthy Adults.*

5.2.4.2 Fair trade, industry competitiveness and minimum effective regulation

In accordance with FSANZ's statutory objectives, i.e. the 'High Order' Policy Principles of the Policy Guideline, 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 COAG and the New Zealand Code of Good Regulatory Practice.

Currently permissions exist in the Code for the addition of certain vitamins to other water-based 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 formulated beverages i.e. hydration.

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

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 Formulated Beverages Supermarket Surveys, the majority of formulated beverages in Australia and New Zealand currently contain the following B vitamins: thiamin; riboflavin; niacin; folate; pantothenic acid; vitamin B_6; and vitamin B_{12}.

Therefore, in the interest of minimum effective regulation, industry competitiveness and fair-trading, and in the absence of public health and safety concerns, the following vitamins will also be permitted for addition to formulated beverages in the amounts requested by the Applicant.

Vitamins
Beta-carotene
Vitamin C
Thiamin
Niacin
Pantothenic acid
Vitamin B_{12}

5.2.4.3 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 these nutrients are to be permitted in formulated beverages, the above permitted forms will be included in the Schedule to Standard 1.1.1.

5.2.4.4 Conclusion

On the basis of public health and safety which is underpinned by the best available scientific evidence, and having regard to: Ministerial policy guidance; the promotion of fair-trading; the desirability for an efficient and competitive food industry; and minimum effective regulation; the following vitamins and minerals are permitted to be added to formulated beverages in the amounts requested by the Applicant:

Vitamins	Minerals
Riboflavin	Calcium
Folate	Iodine
Vitamin B_6	Iron
Vitamin D	Magnesium
Vitamin E	Selenium
Beta-carotene	
Vitamin C	
Thiamin	
Niacin	
Pantothenic acid	
Vitamin B_{12}	

5.2.5 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 'energy drinks' which are prohibited from being mixed with other non-alcoholic beverages[56]. 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.* It is recognised that formulated beverages unless unambiguously described can 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 formulated beverages as ingredients in other foods.

Consequently, FSANZ will maintain a prohibition on the mixing of formulated beverages 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 formulated beverages.

5.2.6 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.

Under current labelling requirements, an added vitamin or mineral must be listed in the ingredient list and if a nutrition content claim is made in relation to a food, the nutrient is required to be listed in the Nutrition Information Panel on the label.

[56] 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 formulated caffeinated beverages as ingredients in other non-alcoholic beverages.

The Policy Guideline states that *there should be no specific labelling requirements for fortified food, with the same principles applying to non-fortified food*.

5.2.6.1 Vitamin and mineral content claims

The Applicant requested that formulated beverages be permitted to carry claims of 'source' or 'good source' for vitamins and minerals. These claims are permitted under Standard 1.3.2 – Vitamins and Minerals provided the food is a 'claimable food' and a reference quantity of the proposed food for fortification contains at least 10% (source) or 25% (good source) of the recommended dietary intake (RDI) per reference quantity. Given formulated beverages meet the definition of a 'claimable food' and the amounts requested by the Applicant for addition to formulated beverages represent 25% of the RDI (and 100% in the case of vitamin C), vitamin and mineral claims will be permitted for formulated beverages in accordance with the Standard. This approach is consistent with permissions for other fortified general-purpose foods.

5.2.6.2 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 formulated beverages.

5.2.6.4 Prescribed name

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

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

As noted above, formulated beverages will be classified as general-purpose foods. General-purpose foods are not required to carry a prescribed name but must comply with the provisions of 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*. It is appropriate that the same approach be applied to formulated beverages as per other fortified general-purpose foods.

Core labelling elements such as the ingredients list and the Nutrition Information Panel will provide a reasonable level of product information which can be further complemented by the use of nutrient content claims. This information, in conjunction with the generic provisions of Standard 1.2.2 is considered sufficient to differentiate formulated beverages from other beverages. Furthermore, the defining compositional requirements will also assist product identification and enforcement. Hence, formulated beverages will not be required to carry a prescribed name.

5.2.6.5 Mandatory labelling statements for formulated beverages

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.

FSANZ's *Labelling – A Risk Management Framework for Decision Making* document (Draft, March 2003) provides specific guidance as to the appropriate use of advisory statements. An advisory statement should be used when:

- the general public or the sub-population is exposed to a significant potential risk to health but the risk is not life threatening, or

- when guidance about use of a food is needed to protect public health and safety.

Advisory statements hold most value when consumers are prompted to scrutinise food labels, for example when they are at risk of consumption of particular foods due to allergy. The conclusion from the risk assessment in Section 5.1 has not identified any risks to the broader population from consumption of formulated beverages. Furthermore, the permitted vitamins and minerals to be added to formulated beverages are relatively comparable with permissions for other fortified general-purpose foods. These fortified foods are not required to carry any additional advisory statements in relation to dietary advice and/or food selection. On this basis, FSANZ is not requiring any mandatory labelling statements on formulated beverages.

5.2.6.6 Conclusion

The generic labelling requirements contained in Chapter 1 of the Code provide consumers with factual information as to the amounts of fortificant in the food. These labelling requirements are also in accordance with the additional Policy Guidance. Therefore FSANZ is not proposing any specific labelling requirements for formulated beverages.

5.2.7 Food additives

The Applicant has requested permission for use of a wide range of food additives in formulated beverages. As previously indicated, FSANZ's risk assessment found no public health and safety concerns with the requested food additive permissions (see Section 5.1.3). Therefore, the following section summarises the findings of the Food Technology Report (as at Attachment 9), which considered the technological justification for the requested food additives, and discusses a number issues consequential to consideration of food additives since Draft Assessment.

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).

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 this Application 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 the requested food additive permissions for formulated beverages and those currently permitted for comparable products. 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.

5.2.7.1 Consequential amendments to food additive permissions

Since this Application was submitted there have been two changes to food additive permissions for category 14.1.3 – Water based flavoured drinks. These recent amendments need to be reflected in the permissions sought by the Applicant since they wish formulated beverages to have comparable food additive permissions to water based flavoured drinks. A new intense sweetener, aspartame-acesulphame (called TwinSweet as a trademark) with a maximum permitted level of 6,800 mg/kg has been approved. This sweetener is a combination of two already approved intense sweeteners, being aspartame and acesulphame potassium. Similarly to incorporate the outcome of a recent approval (Application A469), the permission for saccharin for category 14.1.3 - Water based flavoured drinks has been increased from 80 mg/kg to 150 mg/kg.

5.2.7.2 Requirements for use of intense sweeteners

As formulated beverages will need to meet a compositional criterion for sugar of not greater than 7.5 g/100 ml (7.5%), the use of intense sweeteners may be required to produce formulated beverages with comparable sweetness to water based flavoured drinks or fruit juice products. Comparable products have a sweetness of 10 or 11% sugar or greater. Permitting the use of intense sweeteners in association with the compositional criterion will allow the manufacture of commercially acceptable products with comparable sweetness.

However, currently clause 4 of Standard 1.3.1 restricts use of sweeteners as follows:

> *Save where otherwise expressly stated in Schedule 1 and not withstanding any specific level specified in a Schedule to this Standard, intense sweeteners may only be added to food as a flavour enhancer or in an amount necessary to replace, either wholly or partially, the sweetness normally provided by sugars.*

Therefore, exempting formulated beverages from the requirements of clause 4 allows the sweetness to be greater than that achieved from the compositional criterion of 7.5 g/100 ml. This means it is a special case comparable to brewed soft drinks and chewing gum where the clause 4 restrictions also do not apply. A qualification statement 'clause 4 limits do not apply' is added against the intense sweetener approvals for formulated beverages in Schedule 1 of Standard 1.3.1. This qualification is comparable to qualifications listed for chewing gum and bubble gum contained in category 5 - Confectionery and category 14.1.3.1 - Brewed soft drink.

5.2.7.3 Conclusion

The requested food additives are technologically justified for their proposed use in formulated beverages 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. Therefore, on the basis of the dietary exposure assessment for food additives which concludes that the requested 57 food additives/additive groups to formulated beverages do not raise any public health and safety concerns, FSANZ is permitting their addition to formulated beverages.

5.2.8 Issues raised in submissions

In response to the Draft Assessment submitters raised a number of relevant issues. These included:

- implementation of Ministerial policy guidance;
- vitamin permissions on the basis of fair trading/industry competitiveness;
- definition of 'health benefit';
- appropriateness of food vehicle;
- risk of obesity and impact on dental health;
- application of a sugar restriction to formulated beverages;
- the role of food regulation in public health;
- the scope and purpose of formulated beverages;
- bioavailability of vitamins and minerals in formulated beverages;
- labelling of formulated beverages;

- potential to mislead consumers;
- food additives; and
- currency of data used for risk assessment.

Consideration has been given to these submissions in the preparation of this Final Assessment. Some of the issues raised however are no longer relevant given the amended scope of the Application subsequent to Draft Assessment. A full discussion of the issues is at Attachment 3.

5.2.9 Risk management summary

In summary, FSANZ is recommending the following risk management approach for formulated beverages:

- classification of formulated beverages as a general-purpose food;

- inclusion of a definition for formulated beverages in the Code, in association with a maximum compositional criteria of 24% fruit ingredients and total sugar content of 7.5 g/100 ml;

- application of generic labelling requirements to formulated beverages;

- permissions for the range of food additives requested by the Applicant (as detailed in Attachment 9);

- consequential amendments to relevant intense sweetener permissions and their condition of use; 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	✓	✓
Thiamin	0.28 mg	✓	✓
Riboflavin	0.43 mg	✓	✓
Niacin	2.5 mg	✓	✓
Folate	50 µg folic acid	✓	✓
Vitamin B_6	0.4 mg pyridoxine	✓	✓
Vitamin B_{12}	0.5 µg	✓	✓
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	✓	✓
Pantothenic Acid	1.3 mg	✓	✓

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*
Minerals			
Calcium	200 mg	✓	✓
Iodine	38 μg	✓	✓
Iron	3 mg	✓	✓
Magnesium	80 mg	✓	✓
Selenium	17.5 μg (inorganic and organic forms)	✓	✓

* 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 Draft Assessment, three regulatory options were proposed: maintain status quo (Option 1); permit the addition of a defined set of vitamins and minerals to formulated beverages (excluding cordials) with certain compositional requirements (Option 2); and permit the addition of vitamins and minerals to formulated beverages as requested by the Applicant without any other compositional requirements (Option 3). However, the Applicant has since amended Application A470 to exclude cordials and reduce the number of requested vitamin and mineral permissions. Therefore the following three regulatory options are now being proposed at Final Assessment.

6.1 Option 1 – Maintain *Status Quo*

Under this Option, there would be no change to the current regulatory arrangements for formulated beverages. Formulated beverages would continue to be manufactured under the NZDSR and sold in New Zealand and/or exported to Australia.

In Australia, without specific formulated beverages provisions in the Code, beverage manufacturers would have to continue manufacturing formulated beverages using the existing Sports Foods Standard (with specific mandatory labelling requirements), which is not intended to regulate formulated beverages.

6.2 Option 2 – Amend the Code to permit the addition of vitamins and minerals to formulated beverages as requested by the Applicant with additional specific compositional requirements.

Under this Option, formulated beverages 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 compositional requirements for fruit ingredient and sugar content of formulated beverages. This Option would allow Australian manufacturers to access the formulated beverages market without having to utilise the existing Sports Foods Standard.

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

Option 3 includes permission for the addition of vitamins and minerals as requested by the Applicant but without any additional compositional requirements e.g. no compositional criteria on the fruit ingredients or sugar content of formulated beverages.

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 formulated beverages, importers of formulated beverages into Australia, and the non-alcoholic beverage industry in New Zealand that currently manufactures formulated beverages;

- consumers of formulated beverages 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 submissions to the Draft Assessment Report, market intelligence on formulated beverages provided by the Applicant, interviews with the Applicant on current conditions in the Australian market, research commissioned and undertaken by FSANZ into the formulated beverage 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 formulated beverages. However, some manufacturers are using the Sports Food Standard to produce formulated beverages, 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 formulated beverages 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 formulated beverages as a generally available consumer product: it would diminish consumer perceptions, marketing and distribution of the products. Hence the lack of a specific formulated beverage 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 formulated beverage 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 formulated beverages market that Australian industry cannot participate in. Market intelligence indicates growth of up to 10% per annum may be possible in the next few years, fading to around 5% per annum in five years time. These growth rates are significantly stronger than for the general soft drinks market, of a little over 1% per annum, reflecting the difference between a small developing market and a large mature market. On the basis of such future growth, the Australian formulated beverage 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 the Australian industry is disadvantaged, the 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 formulated beverages market is supplied by imports from New Zealand. The extent of 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 formulated beverages and one company in particular was highly innovative and now dominates this product category. The local market has responded well to the offering. Formulated beverages 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 formulated beverages 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 formulated beverages, of around $A50 million and $NZ17 million respectively in 2004. Most formulated beverages 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 formulated beverage 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 formulated beverages.

Australian consumers are unlikely to be aware that most formulated beverages are imported from New Zealand. They also are unlikely to perceive any restrictions on their formulated beverage 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 formulated beverages they purchase, because one-fifth of the Australian market is manufactured by local companies under the Sports Food Standard. 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 formulated beverages, 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 food-type dietary supplements could involve over-exposure and potential harm. Most consumers would be unaware of any potential risks associated with their consumption of food-type dietary supplements and formulated beverages 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 Sports Food 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 formulated beverages 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 medicine interface will continue, as will the inappropriate application of the existing Sports Food Standard to formulated beverages.

By maintaining the *status quo*, it is likely that the Australian Government in particular will continue to experience 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 Sports Food Standard; the NZDSR; or is simply non-compliant with the Code. If most formulated beverages 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 vitamins and minerals as requested by the Applicant to formulated beverages with additional specific compositional requirements.

7.3.2.1 Impacts on Australian Industry

The compositional requirements under Option 2 would not affect consumer perceptions of formulated beverages and hence the Australian industry could compete effectively with most of the current range of New Zealand imports. The exception would be the few New Zealand imports with a higher sugar content i.e. greater than the compositional criterion of 7.5 g sugar per 100 ml, which would be difficult to compete with directly except where intense sweeteners are used to achieve an acceptable level of sweetness.

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

Australian industry would be expected to switch to local manufacture (to avoid high transport costs) and promote their products. They would immediately seek to compete with the New Zealand market leader of formulated beverages 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 formulated beverages. The Australian market has lagged behind international consumer trends in formulated beverages and hence it offers opportunities for development as Australia catches up to international consumer levels. Market intelligence described the Australian formulated beverage market as 'extremely small, underdeveloped and fragmented' and 'still in its infancy', indicating substantial upside to further development. When global formulated beverage markets developed beyond the infancy stage, they grew at rates in excess of 20% per annum. Hence the market intelligence outlook for Australia of up to 10% per annum in the next few years, fading to 5% per annum in five years, is possible. Overall the impact would be beneficial to the Australian non-alcoholic beverage industry.

Those businesses that currently manufacture formulated beverages under the Sports Foods 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 formulated beverages 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 formulated beverages.

7.3.2.2 Impacts on New Zealand Industry

Under this Option, New Zealand beverage companies have a choice: they could elect to continue to produce formulated beverages 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 other than on exporters who may lose market share to Australian competitors. If they elect to produce under the new permissions in the Code, then the majority of formulated beverages would need to be reformulated to meet compositional requirements. A few products would have to remove non-permitted vitamins and/or minerals such as vitamin A and zinc. The majority of formulated beverages 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 compositional sugar criterion could be significant to those formulated beverages with higher sugar levels and might adversely affect their continuing acceptance by consumers, particularly if the use of intense sweeteners is not considered a acceptable alternative. Though, the number of products affected in this way is believed to be in the minority (i.e. four).

It is difficult to predict what industry's response would be to the new permissions in the Code. Previously, in similar circumstances[57], 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 food-type dietary supplements (which include formulated beverages) to be regulated under the Code. However, the prospect of incurring costs to reformulate existing products in all probability would sway New Zealand industry in the short term at least to continue to produce under the NZDSR.

In the short term while New Zealand retains the NZDSR there will continue to be ramifications for trans-Tasman trade. New Zealand formulated beverages that do not comply with the proposed food standard would still be able to be sold on the Australian market under the TTMRA.

As noted previously, 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 formulated beverages to their associated companies in Australia would discontinue these small additional volumes of production, and avoid their company incurring unnecessary and high transport costs.

[57] Standard 2.6.4 – Formulated Caffeinated Beverages, gazetted August 2001.

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 formulated beverages markets in Australia and New Zealand. It would immediately face competition in Australia from local producers and inevitably 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 formulated beverage 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 formulated beverage market may prove attractive to small producers with niche products.

7.3.2.3 Impacts on Consumers

The most likely scenario for Option 2 in the short term would be that the Australian industry would produce formulated beverages 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 formulated beverages on the market.

The new permissions would facilitate greater competition in the Australian market. Over time, as the formulated beverage 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 formulated beverages 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 limited and is therefore unlikely to increase sugar consumption which in turn should not contribute to the potential problems of obesity (nor the chronic diseases associated with obesity) and poor dental health. 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.

In comparison with the Option 1, consumers will benefit to the extent that Australian-produced formulated beverages displace other formulated beverages products that are non-compliant with the Code, and to the extent that New Zealand industry chooses to produce under the Code rather than the NZDSR. The few formulated beverages with higher than usual sugar content will probably continue to be produced in New Zealand under the NZDSR, while they are still in force, and exported to Australia under the TTMRA, as at present. This situation represents a continuation of the status quo and, in comparison with Option 1, does not alter the impact on consumers.

Impacts can occur when consumers substitute formulated beverages for other products. Stakeholders have provided evidence, albeit limited, which suggests two types of substitution. The first is the substitution of formulated beverages that are compliant with the Code for soft drinks. This may potentially benefit consumers by reducing their sugar and energy intakes, thereby reducing their risk of obesity. The second substitution is where consumers may believe that by consuming formulated beverages they need to be less concerned about their intake of other foods such as fruit and vegetables. In this case, consumers would incur the costs of an unbalanced and inadequate diet. Although market research[58] suggests that consumers generally substitute products for 'like' products e.g. a beverage with another similar beverage. Therefore the first substitution suggested above is in all probability the more likely scenario of the two.

7.3.2.4 Impacts on Government Enforcement Agencies

In Australia the requirements of the two pertinent provisions in the Code – the new formulated beverage permission and the Sports Food 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 at sometime in the future and for food-type dietary supplements (including formulated beverages) 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 formulated beverages 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*.

The new permissions are more restrictive than the NZDSR in relation to compositional requirements, however this should not impact on the enforcement burden in New Zealand given products manufactured under the NZDSR are required to be labelled as 'dietary supplement' hence distinguishing them from formulated beverages manufactured under the Code.

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

7.3.3.1 Impacts on Industry

The impacts on industry are essentially the same as outlined in the Option above, except that there is potentially less costs associated with Option 3 as having no compositional requirement on sugar or fruit juice content may negate the need for re-formulation.

[58] TNS Social Research (2005) Analysis of fortification of foods with calcium research. A report commissioned by FSANZ.

This is likely to be of greatest advantage to the existing formulated beverage range produced by New Zealand industry.

Furthermore, not imposing compositional requirements on the sugar and fruit juice content of formulated beverages provides industry with greater opportunity for future product innovation. However this is likely to more of a long-term phenomenon rather than being conspicuous in the short term.

As per Option 2, New Zealand beverage companies could elect to continue to produce formulated beverages under the NZDSR, or to produce formulated beverages under the new permissions in the Code. However without any other compositional restrictions, there is perhaps more incentive for New Zealand manufacturers to move away from the NZDSR.

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 formulated beverages.

7.3.3.2 Impacts on Consumers

The range and character of formulated beverages 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 absence of a defining compositional sugar level can potentially contribute to the problem of obesity and the chronic diseases associated with obesity, as well as adversely impacting on dental health should manufacturers choose to produce products with high sugar levels. In these circumstances consumers potentially could incur costs to their health and well-being. The application of this defining element also reduces the likelihood that consumers who consider formulated beverages to be healthier alternatives to more traditional soft drinks will be misled regarding the nutritional quality of formulated beverages.

7.3.3.3 Impacts on Government Enforcement Agencies

The impact of Option 3 on government enforcement agencies is similar to that outlined in Option 2 above. Although, allowing formulated beverages to contain higher amounts of fruit juice could impede enforcement agencies clearly distinguishing formulated beverages from other fruit juice drink products (which have different fortification permissions). This possible ambiguity may result in increased enforcement costs; the scale of which is unclear.

8. Consultation

8.1 Public Consultation

8.1.1 Initial Assessment

The Initial Assessment Report for A470 was available for public consultation from 15 January 2003 to 26 February 2003. A total of 19 submissions were received, with 14 of these from Australia, two from New Zealand and three representing Australasian interests.

Of these 19 submitters, 13 submissions were from the industry sector, 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 of maintaining the *status quo* and supporting an amendment to the Code. One submitter did not state any preferred regulatory approach.

8.1.2 Draft Assessment

FSANZ received a total of 30 written submissions in response to the Draft Assessment Report during the public consultation period from 25 May 2005 to 6 July 2005.
Of these, 22 were from Australia, four from New Zealand, two from Australasia and two represented international interests. Submissions received from the industry sector totalled 14. There were also eight submissions from government, six from public health organisations and/or professionals and two from consumer groups and individual consumers. Two late submissions were lodged after the closing date.

Submitters' views varied somewhat between the three proposed regulatory options. The majority of submitters (16) supported an amendment to the Code to permit formulated beverages (Option 2). Of these, four submitters noted strong reservations with another nine suggesting modifications to this option. Seven submitters supported maintaining the *status quo* (Option 1); two of these submitters identified Option 2 as their next preferred option. One submitter did not indicate a preferred regulatory approach whilst five submitters rejected all three options.

Although the majority of submitters supported Option 2, primarily because of the inequitable trade situation for Australian beverage manufacturers, most submitters did so either noting reservations or suggesting modifications to Option 2. These reservations and/or modifications related mainly to the scope of the Application i.e. inequity for other beverage categories with respect to fortification permissions, the appropriateness of formulated beverages as food vehicles for voluntary fortification and the proposed compositional restrictions (sugar and fruit ingredients).

Submitters' views on the proposed sugar limit for formulated beverages were the most divergent. In general, government, public health and consumer stakeholders supported applying a more rigid restriction whereas industry were opposed to the application of any limit on sugar content.

Submitters expressed concerns about increased sugar intakes from formulated beverages and the link with obesity and poor dental health, inconsistency with dietary guidelines that encourage moderate sugar consumption and the potential for consumers to be misled as to the nutritional quality of formulated beverages. Industry on the over hand cited lack of evidence and scientific justification that formulated beverages will adversely impact on sugar and energy intakes.

Given the subsequent amendment to the Application since Draft Assessment the difference now between Option 2 and 3 relates purely to the application of the specific compositional requirements (i.e. limit on total sugar and fruit ingredients) to formulated beverages.

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 formulated beverages rather these products appear to be included in countries fortification policies more broadly. This approach is reflected in the formulated beverage permissions to be contained within Standard 1.3.2 – Vitamins and Minerals of the Code.

Amending the Code to permit formulated beverages 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 formulated beverage regulations was made to the WTO in accordance with the WTO Technical Barrier to Trade Agreement. No comments were received in relation to this matter.

9. Conclusion and Recommendation

Option 2 permits the addition of a discrete set of vitamins and minerals to formulated beverages, which do not pose any public health and safety concerns, in addition to compositional criteria for total sugar and fruit ingredient 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 formulated beverages.

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 formulated beverages 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 formulated beverages.

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 formulated beverages 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.

Option 2 provides a framework for the non-alcoholic beverage industry in Australia and New Zealand to produce formulated beverages under a common standard. If the New Zealand industry continued to produce formulated beverages 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 formulated beverages, 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 formulated beverages as requested by the Applicant without any other specific compositional requirements, provides greater net-benefits to industry compared with Option 1. These benefits to industry also exceed the benefits from Option 2. Under Option 3, manufacturers are not restricted by additional compositional requirements on sugar and fruit juice content, a feature that provides for greater product innovation that may be discernible over the longer term. However, when these innovative products emerge consumers could incur costs because there is no limit on total sugar levels and hence no protection from the risks of obesity or diminished dental health. These are serious risks and the potential costs on consumers are considered to outweigh the benefit to industry of greater scope for innovation. Hence the net-benefits from Option 2, which protects against these risks, are considered to exceed those of Option 3.

Overall, Option 2 is the preferred regulatory option.

FSANZ has undertaken an assessment, using the best evidence available, of the draft variations to the Code (Attachment 1), incorporating defined vitamin and mineral permissions, specific compositional requirements, and a definition for formulated beverages, and considers that these draft variations be approved for the following reasons:

- the regulation of formulated beverages provides assurance for consumers regarding the protection of public health and safety by:

    - permitting the safe addition of vitamins and minerals to formulated beverages;
    - permitting the addition of vitamins and minerals to formulated beverages where an inadequacy or deficiency exists; and
    - setting a compositional requirement on the total sugar content of formulated beverages;

- regulation of formulated beverages ensures certainty for industry balanced against the need to provide informed 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 the COAG principles, and are therefore consistent with Ministerial policy guidance on voluntary fortification.

- the permitted range of vitamins and minerals is consistent with the principles of minimum effective regulation, the desirability of an internationally competitive food industry 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 formulated beverages in the Code promotes equity by providing a regulation which enables the manufacture of formulated beverages in Australia;

- the explicit recognition of formulated beverages 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 net benefits of permitting formulated beverages outweigh any potential costs to affected parties.

The Office of Regulatory Review has considered the regulatory impact statement for this Application and considers it as adequate.

10. Implementation and review

FSANZ believes the public health and safety underpinning the decision to permit the addition of vitamins and minerals to formulated beverages is robust and based on sound science. It acknowledges however, that there are some uncertainties underlying the assumptions that have been made at Final Assessment, particularly in relation to substitution patterns.

In addition, FSANZ is aware that some stakeholders have expressed concerns about the possible future impact of such fortification permissions. In an effort to provide a greater level of assurance for stakeholders, a package of measures will be introduced to review the impact of this and future voluntary fortification permissions.

The key elements of this package will include:

- a review to examine the impact of this and future voluntary fortification permissions over the next five years;

- a new proposal to examine vitamin and mineral content claims with a view to aligning them with the new health claims Standard; and

- a workshop for FSANZ staff and jurisdictions to consider and potentially solve a range of issues relevant to voluntary fortification.

The review process will also provide an opportunity for FSANZ's assumptions to be evaluated.

Following consideration and approval of the Final Assessment Report by the FSANZ Board, a notification will be made to the Ministerial Council. Subject to any request from the Ministerial Council for a review, the amendments to the Code with respect to Standard 1.3.2 – Vitamins and Minerals, and other relevant Standards, would come into effect shortly thereafter upon gazettal.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Amendments to Application A470 – Formulated Beverages
3. Response to issues raised by Submitters
4. Summary of 2005 Formulated Beverages Supermarket 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
11. Excerpt from the *New Zealand Dietary Supplements Regulations 1985*
12. Summary of Food-Type Dietary Supplement Consumer Research

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	Glycerol esters of wood rosins	100	mg/kg		
480	Dioctyl sodium sulphosuccinate	10	mg/kg		
950	Acesulphame potassium	3000	mg/kg		
951	Aspartame	GMP			
954	Saccharin	150	mg/kg		
955	Sucralose	GMP			Clause 4 limits do not apply
956	Alitame	40	mg/kg		
957	Thaumatin	GMP			
961	Neotame	GMP			
962	Aspartame-acesulphame salt	6800	mg/kg		

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

[3.1] *inserting in the* Table to clause 3 –

Formulated Beverages		Vitamin C	40 mg (100%)	
		Carotene forms of Vitamin A	200 µg (25%)	
		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 B6	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
(g) orange peel extract; and
(h) mineral water; and
(i) 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 –

(a) carbon dioxide; or
(b) caffeine.

(3) A formulated beverage must not be mixed with other beverages.

Editorial note:

Formulated beverages are liquid products which are sold in a form designed to be consumed as is, that is, without the need to reconstitute or add further ingredients.

Attachment 2

Subsequent Amendments to Application A470 – Formulated Beverages

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 was necessary to enable a comprehensive assessment of the Application to be completed.

The statutory timeframe was also extended as a result of the ANZFA to FSANZ transition period[59], a delay in the receipt of fees; and the complexity and volume of work to be undertaken[60].

Since the release of the Draft Assessment Report, the final due date has been revised to 19 September 2005.

Summary of Amendments

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 formulated beverages:
    - 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.

[59] 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

[60] extension of the timeframe by six months as permitted by section 35(2) of the FSANZ Act

- 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.

- vitamin and mineral 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.

09.08.05 Withdrawal of request for cordial to be included in the definition of formulated beverages.

Amendment to reduce the requested number of vitamin and mineral permissions from 23 to 16, thus excluding vitamin A, copper, iodine, iron, molybdenum, manganese and zinc.

Attachment 3

Response to Issues Raised by Submitters at Draft Assessment of Application A470 – Formulated Beverages

This section addresses issues raised by submitters at Draft Assessment. A full summary of submitters comments is at Attachment 10.

Please note, a number of submitters provided comment on several issues, which, at the time, were considered to have direct relevance to the regulation of formulated beverages. These included comments in relation to the risk assessment behind the exclusion of specific vitamins and minerals (vitamin A, copper, manganese, molybdenum and zinc) and the exclusion of cordials from the definition of formulated beverages. In light of the subsequent amendments to the Application, these issues are no longer considered relevant to the consideration of this Application and are therefore not addressed below.

1. Fortification Policy Guideline[61]

1.1 Consistency with Policy

A number of submitters (two government, two industry, two public health and one consumer) expressed concern that FSANZ's assessment was inconsistent with policy guidance. Specifically, that permitting the voluntary fortification of formulated beverages would promote consumption patterns inconsistent with national nutrition policy and guidelines, and increase consumption of foods high in sugar, fat and salt.

Four submitters (three government and one public health) considered it inappropriate for vitamins and minerals without any identified nutrition need and/or health benefit to be permitted on the premise of market fairness i.e. where permissions exist for similar products in the Code. In comparison, industry submitters supported the proposed vitamin and mineral permissions, as they would provide greater trade opportunities for manufacturers.

Response

In assessing applications, FSANZ must consider all its statutory objectives in accordance with the FSANZ Act. In addition to the three priority objectives of protection of public health and safety, provision of information for informed choice and prevention of misleading conduct, FSANZ must also have regard to a number of other matters including amongst others promotion of fair-trading, the desirability for an efficient and competitive food industry and Ministerial Policy Guidance. Initially, FSANZ does this without assigning precedence to any of these matters, however 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.

The Policy Guideline includes 'High Order' Policy Principles, which are FSANZ's statutory objectives, and therefore take precedence over policy guidance specifically provided on voluntary fortification.

[61] Australian and New Zealand Food Regulation Ministerial Council *Policy Guideline Fortification of Food with Vitamins and Minerals*.

In the case of this Application, FSANZ has in accordance with its priority objectives considered public health and safety, first and foremost. FSANZ's risk assessment has considered the benefits (nutritional need and benefit) and potential detrimental effects from the addition of vitamins and minerals to formulated beverages as well as impacts from excess sugar and energy intakes.

Consideration has also been given to the appropriateness of formulated beverages as food vehicles for voluntary fortification. In particular, whether formulated beverages have the potential to increase sugar intakes. The conclusion from the dietary modelling indicates this is unlikely. Furthermore, the compositional criterion for total sugar being applied to formulated beverages is consistent with policy guidance by not promoting consumption patterns inconsistent with nutrition policy and guidelines. It also reduces the potential for formulated beverages to promote increased consumption of foods high in sugar.

In relation to the vitamin permissions, FSANZ has, accordance with its other statutory objectives, i.e. the 'High Order' Policy Principles, also given regard to other relevant matters. This has included the ability of formulated beverages to be produced and marketed in an environment of industry competitiveness and fair-trade. This has involved applying the principle of minimum effective regulation as required by the Council of Australian Governments (COAG)[62] and the New Zealand Code of Good Regulatory Practice. Hence, in the absence of any public health and safety concerns, FSANZ has permitted the addition of certain vitamins where these permissions already exist in the Code already exist for similar beverage products.

1.2 Definition of health benefit

One submitter stated that the interpretation of 'health benefit' in the Nutrition Assessment focused on the reduction of chronic disease risk, with little explanation of increased health status.

Response

At Draft Assessment, 'health benefit' was defined as an increase in health status or reduction in chronic disease risk that is not nutritional in nature, however the term did not extend to pharmacological benefit or treatment of disease. The statement 'increase in health status' was therefore intended to cover those situations where improvements in physiological parameters were the outcomes identified in the scientific literature. Evidence in support of a health benefit was drawn from healthy populations as well as those at-risk or suffering diseases of public health significance. The selected list of diseases were those that contribute to more than 2% disability adjusted life years in the Australian and New Zealand burden of disease registers[63,64].

[62] 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).
[63] Mathers, C., Vos, T. and Stevenson, C. (1999) *The burden of disease and injury in Australia.* Australian Institute of Health and Welfare, Canberra.
[64] Ministry of Health (2001) *The burden of disease and injury in New Zealand*. New Zealand Ministry of Health, Wellington.

In FSANZ's review of the scientific literature, evidence was sought on improvement in physiological parameters separate from reduction of chronic disease risk but very little information at intakes above the RDI was found. As such, the definition of 'health benefit' provided at Draft Assessment remains unchanged at Final Assessment.

2. Appropriateness of food vehicle

2.1 Formulated beverages as food vehicles for fortification

Submitters expressed concerns about formulated beverages being inappropriate food vehicles for voluntary fortification. Some believe that formulated beverages are 'nutritionally inferior' as vehicles for fortification, will encourage consumption of unhealthy beverages, and are inconsistent with dietary guidelines that encourage drinking of water and milk rather than sugar containing beverages.

Response

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. Under this Framework, the introduction of a newly fortified food into the market can result in consumers:

- substituting the fortified food for the same non-fortified food (substitution);
- displacing other food product(s) with the fortified food (displacement);
- increasing their intake of the food (or food category) because of the fortification (addition); and/or
- not including the fortified food in their diet **(avoidance)**.

In this case, we have concluded that consumers will largely **substitute** formulated beverages for their unfortified counterparts – that is, for other water-based beverages.

At Final Assessment, FSANZ has undertaken dietary modelling to establish determine whether formulated beverages may adversely affect sugar intakes (see Attachment 5). Whilst the assessment has shown that the relative impact depends on the pattern of substitution, it is unlikely to increase per capita total sugar intakes. Furthermore, the application of a compositional criterion for total sugar is a defining element of formulated beverages and positions these products as being a 'healthier' beverage alternative when compared to traditional water-based beverages such as soft drinks.

2.1 Sugar content in relation to overweight, obesity and dental health

A number of submitters commented on the risk to overweight and obesity from sugar-containing beverages. Several submitters provided evidence in support of the Nutrition Assessment findings, while other submitters commented that sugar intake can also impact on dental health. Submissions also indicated that the acidity of formulated beverages is a concern for dental health in addition to the sugar content.

Industry submitters in general did not support the application of a sugar restriction. In particular, the Applicant provided a response to the Draft Assessment opposing the restriction, and included evidence showing that the contribution of energy from non-alcoholic water-based beverages has declined in Australia. The Applicant's material was based on sales data for non-alcoholic water-based beverages, where sales trends for this category have declined over the period of 1997-2004 in Australia. The Applicant combined this information with average sugar contents of non-alcoholic water-based beverages to show a downward trend in energy intake contributions.

The Applicant defined the category 'non-alcoholic water-based beverages' as water-based beverages currently regulated by Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drinks, Standard 2.6.4 – Formulated Caffeinated Beverages, and Standard 2.9.4 – Formulated Supplementary Sports Foods. The Applicant's definition does not include fruit juices, tea, coffee or milk.

Response

FSANZ recognises the significance of the issues surrounding the sugar content of formulated beverages for submitters. Therefore, FSANZ has revisited this issue in the Nutrition Assessment Report at Final Assessment, which includes a more substantial review of the relevant scientific literature. A new section on dental health has been included in recognition of the comments received on dental caries, dental erosion, and on the acidity of formulated beverages. The findings of these assessments are summarised in Section 5.1.1.2 of the main report, and provided in detail at Attachment 5.

The Nutrition Assessment has relied on literature that directly examines the association between sugar-based beverage consumption and overweight/obesity, and the results of dietary modelling on sugar intakes, as a means of determining the risks from the sugar content of formulated beverages.

FSANZ acknowledges the downward trend in sales for some non-alcoholic water-based beverages as demonstrated by the Applicant's data. However, this does not include all beverages encompassed by the term 'sugar-containing' beverages such as fruit juices which could be potentially replaced by formulated beverages. Therefore, FSANZ considers that the dietary modelling of sugar intakes undertaken at Final Assessment (provided in Attachment 5) is a more accurate means of gauging the impact of a formulated beverage category on population sugar intakes.

2.2 Reference quantity/Serving size

Ten submitters commented on the proposed 600 ml reference quantity. Seven submitters expressed concern about the reference quantity citing public health and safety concerns, particularly the sugar content in a 600 ml quantity, the contribution of this to total energy intake and the perceived inconsistency with the Policy Guideline and national nutrition policies. Four submitters questioned the use of a 600 ml reference quantity for reasons such as, it exceeds the reference quantity ascribed to other beverages and may be too large for some groups of the population. Another submitter suggested a 500 ml reference quantity to allow 'source' claims to be made for a serve size of 230 ml i.e. the size of a normal drinking glass.

Response

The serving sizes of formulated beverages are generally larger than the standard serving size for soft drinks, juices and cordials. This reflects the stated function of 'hydration' and the Applicant's requested reference quantity of 600 ml.

As the Applicant has requested a 600 ml reference value, FSANZ must make its assessment using this reference value. Consequently, FSANZ's risk assessment has considered the possible impact of larger serving sizes when assessing the public health and safety risks associated with formulated beverages. In particular, the reference quantity has been considered in assessing the appropriateness of formulated beverages as food vehicles for voluntary fortification.

It should be noted however that the requested reference quantity does not necessarily reflect the potential range of serving sizes for formulated beverage products. For example, it is possible that formulated beverages will be available in smaller serving sizes (e.g. 250 ml).

3. Potential to Mislead Consumers

3.1 Nutritional quality of formulated beverages

Submitters at Draft Assessment, predominantly those from the public health and government sectors, expressed concern that consumers may be misled as to the nutritional quality of formulated beverages due to the presence of vitamins and minerals. They consider that consumers may perceive formulated beverages to be a healthier beverage alternative and/or an equivalent source of vitamins and minerals for foods such as fruit and vegetables. Many submitter concerns are heightened by the expected marketing of formulated beverages as a 'healthy' addition to the diet, and the use of 'source' claims on product labels by manufacturers.

Response

As with other fortified foods, adequate information needs to be provided to enable consumers to make an informed choice. FSANZ considers the information contained in the nutrition information panel and the ingredient listing, together with the permitted vitamin and mineral claims, will provide consumers with factual information as to the nutrient profile of the food including the type and amounts of fortificant in the formulated beverage.

As part of its assessment of the appropriateness of formulated beverages as food vehicles for fortification, FSANZ has also recognised that there is a potential risk that consumers could be misled as to the nutritional quality of formulated beverages, given the addition of vitamins and minerals may enhance the nutritional attractiveness of formulated beverages which consumers may perceive as 'healthier' beverage alternatives. Applying a compositional requirement on the total sugar content of formulated beverages should minimise this risk and is consistent with policy guidance. The compositional requirement, together with the generic labelling elements mentioned above, should also ensure sufficient information is available to enable consumers to assess the appropriateness of formulated beverages when making food/beverage choices.

3.2 Bioavailability and stability

Some submitters also consider that consumers will be further misled if the vitamin and mineral additions are not stable or bioavailable in the formulated beverage, where consumers are expecting to benefit from the presence of the claimed nutrients.

Response

There are no specific requirements in the Code relating to bioavailability and stability of nutrients in general-purpose foods. However, general provisions in food law and fair trading law, as they relate to misleading and/or deceptive conduct, require manufacturers to consider the total representation of a food and how consumers will interpret information provided on labels. Furthermore, FSANZ is not aware of any evidence to suggest that formulated beverages, with their added vitamins and minerals, are going to 'mislead' consumers any more than traditional food sources.

Bioavailability of vitamins and minerals varies significantly, depending on a wide range of factors, including a physiological status, nutritional status and the type of research method used to calculate the bioavailability. Comparison of gastrointestinal absorption rates among vitamins and minerals – irrespective of whether naturally occurring or supplemental – also show wide variabilities with very few vitamins and minerals attaining complete intestinal absorption, including naturally occurring vitamins and minerals. Therefore, it is not possible to draw definite conclusions on the bioavailability as it applies to any individual food product, nor can it be said that naturally occurring vitamins and minerals are any more bioavailable than their added counterparts.

4. Scope of Application

4.1 Purpose

Three submitters indicated that they did not support regulation of formulated beverages as general-purpose food contending that they fulfilled a specific purpose e.g. vitamin and mineral supplementation.

Response

As discussed in Section 5.2.1.1 of the Final Assessment Report, the Code currently only recognises two purpose categories: general-purpose and special-purpose.

FSANZ had previously identified a possible third purpose category of 'supplemental' during the development of the 'energy drink' standard (Application A394). This was devised to describe a third category of foods seen as having a 'functional' purpose outside the conventional nutritional paradigm. However, the development of Ministerial policy guidance that places fortification with vitamins and minerals predominantly in a nutritional paradigm means consideration of 'supplemental' purpose is no longer appropriate. Consequently, formulated beverages can currently only be regulated as either general- or special-purpose food.

Consequently, as the likely target group for formulated beverages do not have 'particular dietary requirements', and given the anticipated presentation and marketing of these products will be as general-purpose food, it is appropriate that the same approach, including regard for policy guidance, be applied to formulated beverages as per other fortified general-purpose food.

4.2 Definition

Two industry submitters considered the definition of formulated beverages, as proposed at Draft Assessment, to be limited, extremely prescriptive and thus would stifle product innovation. In addition, five other industry submitters requested that the scope of the definition to be extended to include milk, fruit juice[65] and fruit drink. Those submitters who supported the inclusion of milk, argued it would prevent milk from being perceived as nutritionally inferior and that this would be more consistent with national nutrition policies. Similarly, four industry submitters, including two dairy industry submitters, considered permitting fortification of formulated beverages as inequitable for other food products such as dairy products. They considered the approach to be inconsistent with the 'promotion of fair trading' and the desirability for the food industry to be 'working efficiently and competitively'.

One industry submitter also recommended the inclusion of biologically active substances, non-culinary herbs, vegetable juices, spices, tea components and soluble fibre.

Three submitters commented on whether the definition of formulated beverages included powdered beverages, where one submitter considered that the powdered product 'Tang', which is currently sold in South East Asia, would meet the proposed definition as a formulated beverage.

Response

Submitter comments have raised the issue of including other ingredients such as milk and biologically active substances in the scope of the Application. Under the FSANZ Act, there is no statutory mechanism to enable an Applicant or other interested parties to expand the scope of an application once the assessment process has commenced. Therefore the scope of the Application cannot be extended. Notwithstanding this any party can independently lodge a separate application for consideration by FSANZ at any time.

The definition as proposed at Draft Assessment does reflect the range of ingredients as requested by the Applicant. Therefore approval of this Application provides industry with an opportunity for innovation and development of the formulated beverage category within the beverage market.

As the Applicant did not request consideration of concentrated drink bases (powders or liquids) (and also with the exclusion of cordials from the scope of the application), FSANZ has not considered these in its assessment. Therefore, implicit to the definition is that formulated beverages are 'ready to drink' and do not include concentrates or drink bases that can be prepared according to manufacturers' directions following purchase.

[65] Submitters were requesting fruit juice at levels beyond the proposed maximum 24%.

5. Composition of formulated beverages

5.1 Vitamin and mineral permissions

(a) Risk assessment of vitamins and minerals with no adverse effects

Some submitters raised concerns regarding the inclusion of beta-carotene, vitamin C, vitamin D, vitamin E, and selenium, which can potentially cause adverse effects at high levels of intake.

Response

The potential of these vitamins and minerals to result in adverse effects have been examined. A detailed report is in Attachment 6. This assessment concluded that the addition of these vitamins and minerals at a level of 25% RDI per 600 ml would not raise public health and safety concerns, since the dietary intake of these micronutrients would be considerably lower than the levels associated with adverse effects.

(b) Sensitive subpopulations

One submitter disagreed that the identified sensitive subgroups might be at risk, while other submitters questioned the safety and the appropriateness of the risk management for iodine and iron sensitive individuals.

Response

FSANZ's risk assessment has determined that some identified sensitive subgroups might be at risk of adverse effects at levels currently in the diet, and therefore could be at an increased risk when consuming formulated beverages containing iodine or iron. The argument that clinical guidelines on treatment of haemochromatosis do not recommend restriction of iron in the diet, is not relevant for this Application, since these consumers may already be at risk with a normal diet, and adding more to the diet could increase the risk of adverse effects.

As previously discussed (Section 5.2.4.2.1 of the Final Assessment Report), FSANZ considers the potential benefit (given evidence of nutritional inadequacy) to the total population of permitting the addition of iron and iodine to formulated beverages outweighs the risk to a very sub-population of vulnerable individuals. Generic labelling requirements including identification of the presence of iron and iodine is considered appropriate to assist consumers make informed choices in meeting their own particular dietary or health needs.

(c) Impact of permissions on mandatory fortification

Two submitters (one consumer group and one government) questioned if the voluntary fortification of formulated beverages (and other foods) with iodine and folate is appropriate, when mandatory fortification with these nutrients is currently being considered. The consumer group considered that if both voluntary and mandatory fortification for iodine and folate were allowed, the approach will become less controlled and would undermine the public health strategy associated with mandatory fortification.

Response

As noted previously, FSANZ is currently assessing the need for mandatory fortification of the food supply with iodine and folate. In undertaking these assessments, FSANZ will need to consider all sources of iodine and folate in the food supply and may need to reassess iodine and folate permissions in the future, if deemed necessary.

5.2 Bioavailability

Seven submitters commented that bioavailability should be taken into account before permissions are given to add vitamins and minerals to formulated beverages. Specific comments included:

- any standard should ensure that the food industry is made responsible for analytical method development and method validation and bioavailability;
- adding vitamins and minerals to formulated beverages does not guarantee nutritional equivalence to naturally occurring sources;
- consumers may expect the vitamin or mineral in the product has an appropriate level of bioavailability; and
- without bioavailability data, there is no evidence that fortified beverages will address deficiencies or provide health benefits to the general population.

Response

Bioavailability can be influenced by many factors making it a highly variable attribute of vitamins and minerals. Despite the current research methods that have been developed, a large degree of uncertainty remains with any findings on vitamin and mineral bioavailability, as there are a wide variety of modifying factors that can confound results from scientific studies.

Given the uncertainties in the totality of the evidence owing to the many dietary and physiological influences on bioavailability, FSANZ has not been able to draw any definite conclusions on bioavailability as it applies to any individual food product, including formulated beverages. Therefore, it is not possible to assess bioavailability to the extent that many submitters indicated in comments to the Draft Assessment. It is, however, expected that the vitamins and minerals in formulated beverages are bioavailable to varying extents, the same as occurs with natural food sources of vitamins and minerals. This outcome is regarded as sufficient to meet the Policy Guideline that refers to potential effectiveness for voluntary fortification.

FSANZ also considers that it is not necessary for formulated beverage manufacturers to demonstrate bioavailability of fortificants in their products, given the wide range of dietary and physiological influences on bioavailability, and that only limited information will result from single studies to guide any assessment of formulated beverage effectiveness.

5.3 Percent Fruit Ingredients

Submitters' views varied on the maximum percent fruit ingredients being limited to 24%. Eleven submitters commented on this issue, including nine from industry and two public health groups. Of the nine industry submitters only one supported the maximum limit.

The remaining eight rejected the argument for this limit stating that enforcement agencies and consumers would be able to distinguish between fruit drinks and fruit juices, and that there is no technological justification for prescribing this limit. Of these, four submitters considered that fruit ingredients should be permitted up to 50%. One public health submitter also rejected the need for a fruit content limit, as they considered the fruit ingredient content will be limited by the total sugar or energy content that is prescribed. Another public health submitter recommended the fruit juice content be limited to no more than 5%.

Response

As previously discussed in Section 5.2.2 of the Final Assessment Report it is important that formulated beverages are unambiguously described and do not inadvertently act as a means to circumvent other, more appropriate food standards.

Formulated beverages can be considered a sub-category of water-based beverages, which may or may not include fruit ingredients, and by definition contain added vitamins and minerals. Fruit drinks on the other hand, represent a broad category of water-based beverages that must include fruit ingredients, but do not necessarily contain added vitamins and minerals. Given the similarity of ingredients, the primary difference between formulated beverages and fruit drinks therefore lies in the fortification permissions available to each product category.

Since Draft Assessment, FSANZ has examined the composition of formulated beverages with respect to fruit ingredients and sugar content. It should be noted that the proposed total sugar compositional requirement (7.5 g/100 ml) does not preclude fruit drinks (>25% fruit ingredients) from being formulated beverages. In fact, the proposed sugar level allows for the addition of fruit ingredients in amounts greater then 70% depending on the fruit ingredient used. For this reason, it is considered necessary to prescribe a maximum limit for fruit ingredients of 24% so as to provide regulatory clarity and to clearly distinguish formulated beverages from other fruit juice based products, particularly in respect to vitamin and mineral permissions.

6. Labelling

6.1 Vitamin and mineral content claims

Several submitters at Draft Assessment expressed concerns in relation to vitamin and minerals content claims. For the most part these concerns were linked to the potential for claims to mislead consumers as to nutritional quality of formulated beverages. Two public health professionals recommended that claims should be restricted to inclusion in the nutrition information panel only.

Response

The issue relating to the potential to mislead consumers has been discussed earlier in Section 3.

The Policy Guideline for voluntary fortification explicitly states that there should *be no specific labelling requirements for fortified foods with the same principles applying as to non-fortified foods.*

The suggestion to restrict claims to the nutrition information panel only would therefore be inconsistent with policy guidance and the claiming provisions for all other fortified general-purpose foods. Application of this requirement to formulated beverages would thus be inequitable and does not support industry fair-trading or the principles underpinning minimum effective regulation.

6.2 Use of advisory statements on formulated beverages

Submitters at Draft Assessment were divided in their opinions as to the benefit or necessity of such statements. Seven submitters supported the use of warning and/or advisory statements on the labels of formulated beverages, particularly to highlight potential risk of consumption by vulnerable populations such as children and pregnant women, and to inform consumers of the presence of vitamins and minerals in the beverage. Examples of suggested statements included, 'consuming formulated beverages does not replace a healthy diet', 'not recommended for children', and 'dietary supplements are only of use if intake is inadequate'. In contrast, two submitters (one industry and one government) supported the use of generic labelling requirements for formulated beverages, as recommended at Draft Assessment.

Response

Where appropriate, mandatory labelling statements can be used to manage risk. FSANZ's current labelling risk management framework for decision-making provides that:

- a *warning statement* is used where the risk to public safety is potentially life threatening and it can reasonably be assumed that the general population or the specific target group is unaware of the potential safety risk;
- an *advisory statement* is used where the general population or a sub group of the population are largely unaware of a potential, but non life threatening risk to public health and safety and need advice about that risk; and
- *general labelling provisions* should be sufficient to manage risks where the risk to public health and safety is determined to be low because the likelihood of an adverse event occurring is rare and the consequences minor.

Given the risk of formulated beverage consumption on public health and safety has been determined to be low, FSANZ considers the application of a warning statement on formulated beverages to be unjustifiable.

In terms of advisory statements, these hold most value when consumers are prompted to scrutinise food labels, for example when they are at risk of consumption of particular foods e.g. allergy. The conclusion from the risk assessment in Section 5 of the main report has not identified any risks to the broader population from formulated beverage consumption. Furthermore, the vitamins and minerals permissions for formulated beverages are considered to be at moderate levels and are consistent with permissions for other fortified general-purpose food. These fortified foods are not required to carry any additional advisory statements in relation to dietary advice and/or food selection. On this basis, FSANZ is not requiring any mandatory labelling statements on formulated beverages.

It should be noted however, that the rationale underpinning the use of advisory statements is expected to be reviewed as part of a separate FSANZ process.

Should this review identify a demonstrated need for fortified general-purpose foods including formulated beverages to carry mandatory advisory statements, this may require possible future labelling changes.

6.3 Advertising of formulated beverages

Two public health submitters expressed concern about how formulated beverages will be marketed and advertised highlighting a recent example of where consumers have raised concerns over misleading advertising for foods with added vitamins and minerals.

Response

Advertising is addressed in clause 13 of Standard 1.1.1 of the Code, which states:

Advertisements for food must not contain any statement, information, designs or representations which are prohibited by the Code from being included in a label for that food.

This provision encompasses all generic labelling requirements including those for nutrition, health and related claims. Therefore, as with all other foods formulated beverages will also need to comply with this requirement.

7. Food Additives

7.1 Category of formulated beverage additives

One submitter questioned why a separate category was created for formulated beverages in Schedule 1 of Standard 1.3.1 since the permissions already exist in comparable non-alcoholic drinks categories (that is fruit and vegetable juice products, and water based flavoured drinks).

Response

The separate category was created for formulated beverages for the sake of clarity, so that it is obvious to all stakeholders, principally food manufacturers and enforcement authorities, exactly what food additive permissions apply to formulated beverages compared to other drink categories. There are a number of important differences between the two drink categories, which are summarised in Attachment 9 - Food Technology Report. With such differences in food additive permissions between different drink categories, it was considered prudent to create a separate category for formulated beverages to prevent possible misunderstandings.

7.2 Preservatives

One submitter questioned whether in removing ready-to-drink cordials from the list of permitted foods, there was a need to retain the proposed levels of preservatives for the remaining products in the market. Noting alternative available technologies, such as hot-fill or UHT packaging, it was also questioned whether is it necessary to retain permissions for sulphites and benzoates.

Response

The requested permissions for sulphites and benzoates for formulated beverages are comparable to those that are currently permitted for comparable non-formulated products such as category 14.1.3 - Water based flavoured drinks, and 14.1.2.2 - Fruit and vegetable juice products within Schedule 1 of Standard 1.3.1. The use of preservatives in these beverages is to help prevent the growth of spoilage and non-spoilage organisms that can reduce the shelf life and quality of these product, as well as preventing possible health risks.

Not all products (both formulated beverages and their currently approved comparable non-formulated products) are, or will be produced using new technologies that may reduce the requirements of high concentrations of preservatives. Therefore products need to have a reasonable level of protection from spoilage by being able to use preservatives. Even with very good, new modern production and packaging techniques products will still probably require some level of preservatives to ensure safety and quality. Manufacturers will use the minimum amount of preservative to ensure safety and quality, which is required for Good Manufacturing Practice (GMP).

FSANZ has initiated Proposal P298 - Benzoate and Sulphite Permissions in Food, to work with food manufacturers to refine the data for benzoate and sulphite concentrations in food, and if necessary how to best reduce the consumption of these preservatives among the small number of consumers that may exceed the Acceptable Daily Intake (ADI) based upon the survey results.

7.3 Artificial Sweeteners

One submitter suggested that further consideration be given to the implications of increased consumption of artificial sweeteners together with additional labelling statements advising of the presence of artificial sweeteners and the impact of over-consumption on health.

Response

FSANZ commissioned a survey of the consumption of artificial sweeteners as part of its Evaluation Strategy to assess the impact of replacing the former *Australian Food Standards Code* with the *Australia New Zealand Food Standards Code*. This evaluation was published as a FSANZ document, 'Consumption of Intense Sweeteners in Australia and New Zealand', 2004.

The conclusion of the survey was that there were no public health and safety concerns for consumption of intense sweeteners, except for cyclamate. The issue with cyclamate consumption is being addressed in Proposal P287 - Review Of Cyclamate Permissions. FSANZ does not believe there are any health concerns with the consumption of intense sweeteners (aside from the review of cyclamate permissions mentioned). Their presence in food, if used, is indicated in the ingredients label.

8. Dietary Modelling

8.1 Age of the National Nutrition Surveys

Several submitters raised concerns on the age of the National Nutrition Surveys (NNS), and question the accuracy and relevance of this 10-year old data.

Response

FSANZ acknowledges that the New Zealand and Australian National Nutritional Survey (NNS) data are 8 and 10 years old respectively. Conducting dietary modelling based on 1995/1997 NNS food consumption data provides the best estimate currently available of actual consumption of foods and the resulting estimated exposure to a food chemical. It should be noted that while the NNS may not include information regarding some food products that are now available on the market, for staple foods such as breads, cereals, meats, fruits and vegetables and milk etc, which make up the majority of the diet for most Australians and New Zealanders, the data derived from the 1995 NNS is likely to still be representative today (Cook *et al*, 2001)[66].

It is also acknowledged that, since the data were collected for the NNS, there has been an increase in the range of products that are fortified with nutrients. Consequently, the nutrient databases from the NNS may not be entirely representative of the nutrient levels in some foods that are now on the market. Likewise, the limitation of there being no data in DIAMOND on the use of complementary medicines (Australia) or dietary supplements (New Zealand) is also acknowledged.

Where significant uncertainties exist in the data used for dietary modelling, conservative assumptions are used to ensure estimated dietary intakes, and therefore the level of risk, are not underestimated. The assumptions made for the dietary exposure assessments for A470 are outlined in Attachment 7 for nutrient modelling and Attachment 8 for food additive modelling. Examples of these include:

1. in Scenario 1, where the percent market share held by FB was rounded up to be 5%, and where the maximum claimable concentrations of the nutrients in the FB were used in the dietary modelling;

2. where the relevant data were available, the dietary modelling did take into account where products are currently fortified. This was the case for folic acid where it was assumed that breakfast cereals are fortified with folic acid and that the level of folic acid in the breakfast cereal is equal to the labelled quantity of folate for those products; and

3. where the maximum permitted levels were used for some food additives and where it was assumed all products in a food category contained the additive.

66 Cook, T., Rutishauser, I.H.E. and Allsopp, R. (2001) The Bridging Study: comparing results from the 1983, 1985 and 1995 Australian national nutrition surveys, Australian Food and Nutrition Monitoring Unit, Commonwealth Department of Health and Aged Care, Commonwealth of Australia, Canberra

The 1995 NNS data were determined to be not particularly suitable for assessing the change in sugar intakes should FB be permitted on the market, given that beverage consumption has changed since the Australian 1995 NNS was conducted, 2004 market share data from AC Nielsen Scan Track was used to assess whether substitution of selected non-alcoholic beverages by FB would increase total sugars intakes from those beverages only. These data provided a more up-to-date estimate of beverage consumption patterns both to estimate baseline sugar intakes from non-alcoholic beverages, and sugar intakes from FBs based on certain beverages being substituted with FB at 5% or 100% penetration. Even with this recent data on total volumes for different types of beverages in the non-alcoholic beverage market the dietary modelling indicates limited impact on total sugars intake from non-alcoholic beverages due to the introduction of formulated beverages, assuming they are substituted for 'like' drinks.

The dietary modelling is used as a tool to guide risk management decisions. It provides an estimate of intake and a guide to the extent of any potential safety concerns. Two day adjustments have been used where possible to take 'usual intake' into account. FSANZ believes that whilst there are some limitations due to the age of the NNS data used for intake assessments, the overall conclusions and risk management decisions are robust.

8.2 Assumptions made for modelling

(a) Information from the Australian Market Survey 2005 indicates that the maximum recommended daily intake on the product label of formulated beverages range from 600-3600 ml per day for adults. At the upper limit of 3600 ml, this would equate to consumption of 150% of the Recommended Daily Intake for many vitamins and minerals

Response

The intakes of food additives and nutrients were calculated for each individual in the NNS using his or her individual food records from the dietary survey. Therefore, the range of intakes of beverages that people would consume on a daily basis has been taken into account. It would be unrealistic to add the vitamins and minerals intakes from a daily intake of formulated beverage to the intakes from all other foods consumed during the day. Without accurate data on 'actual' consumption of formulated beverages, FSANZ believes that using the beverage consumption data in the NNS for the assessments was the best methodology to use.

(b) One submitter considers that the risks and issues for public health and safety have not adequately taken into account the substitution of milk beverages and water that may result from the additional permissions.

Response

In the Market Share Scenario modelling used in the nutritional benefit assessment, it was assumed that 5% of all non-alcoholic beverages (excluding milk and milk-based beverages) would be replaced with formulated beverages. Bottled water and tap water (as used as a beverage or to make up a beverage) were included in the substitution.

In the 100% Substitution Scenario used in the safety assessment, it was assumed that cordials (excluding those made up from powder), carbonated drinks, fruit juice drinks, sports drinks and bottled waters would be substituted with formulated beverages. In general, it was assumed that formulated beverages would replace 'like' products. Since milk and milk-based beverages are not 'like' products, it was assumed they would not be substituted by formulated beverages.

(c) One submitter was concerned that for modelling all drinks were replaced by fortified beverages, and thereby using a conservative approach

Response

When conducting the dietary modelling for the safety assessment for each vitamin and mineral, FSANZ assumed that only 'like' beverages were substituted with formulated beverages in order to represent likely consumer behaviour. Therefore only fruit juice drinks, carbonated non-alcoholic beverages, cordials, sports drinks and bottled waters were assumed to be substituted by formulated beverages. Beverages such as teas, coffees, tap water, milk (including flavoured), fruit juices and alcoholic beverages were assumed to not be replaced with formulated beverages.

8.3 Food composition data

One submitter was concerned that the use of dietary modelling and food composition data, based on UK and USA data, is only a rough approximation and does not accurately reflect Australian/New Zealand populations or food supply.

Response

The food consumption data used in dietary modelling is as per the 1995 Australian NNS and the 1997 New Zealand NNS. No food consumption data from other countries were used.

For the majority of nutrients, the baseline nutrient concentrations used in the dietary modelling were as used in the assessment of the 1995 and 1997 NNS. Where nutrient data were not available for Australia, New Zealand nutrient data were used and matched to the most appropriate food codes and vice versa for New Zealand. Iodine is the only nutrient where some overseas (British and German) food composition data were used. This was only for a few food groups (tropical fruits with edible peel, and seaweed), which were not major contributors to iodine intakes, and only where Australian and New Zealand data were not available at the time.

The non-Australian/ non-New Zealand data were used to ensure that a dietary intake estimate was conducted including foods across the whole diet. FSANZ is aware of the limitations of using international data. FSANZ staff has assessed the non-Australian/ non-New Zealand data used and the influences on iodine levels in foods. 'Borrowing' composition data from other countries is common practice internationally when constructing food composition data sets, especially when constructing the datasets from limited 'local' information. FSANZ is confident that the non-Australian/ non-New Zealand data sets used are representative of iodine levels in the Australian/ New Zealand counterparts of these foods.

9. Other Issues

9.1 Repeal of New Zealand Dietary Supplements Regulations (NZDSR)

Many submitters also acknowledged the inequality that exists due to the NZDSR, expressing concern that New Zealand manufacturers will be able to continue to manufacture products to these regulations until they are repealed by the New Zealand government, and thus would continue to provide an inequitable situation for fair trade and industry competitiveness between Australia and New Zealand.

Response

The New Zealand Government[67] 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.

Currently, there are a number of parallel processes occurring which directly impact on the future of the NZDSR and the timing of any possible changes to the NZDSR. These include the development of the joint Australian and New Zealand therapeutics agency and policy development by the Ministerial Council on the addition of substances other than vitamins and minerals to food.

Consequently, FSANZ expects that the completion of these concurrent activities will with time assist to clarify the future of the NZDSR.

9.2 Sodium Restriction

One industry submitter at Draft Assessment recommended that the sodium content of formulated beverages should be in line with the Dietary Guidelines.

Response

The proposed definition of formulated beverages generally precludes the addition of sodium or ingredients containing sodium to formulated beverages. Therefore, it is unlikely that the resulting sodium content of formulated beverages, naturally present in ingredients or added as a component of a permitted additive, would be present at a level considered detrimental to health.

In addition, the Dietary Guidelines for Australian Adults[68] reflect the criteria outlined in Standard 1.2.8 of the Code, which stipulates that to claim a food is low in sodium the food must contain no more than 120 mg of sodium per 100 g of the food[69]. The product range identified in the 2005 Australian and New Zealand Formulated Beverages Surveys contained between 2-25 mg sodium per 100 ml. Therefore, assuming 100 ml formulated beverage equates to approximately 100 g formulated beverage, the sodium content of currently available formulated beverages is not considered high and would not warrant a sodium restriction.

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[67] New Zealand Food Safety Authority Discussion Paper No. 01/04 (July 2004) *Proposed Changes to the Dietary Supplements Regulations 1985*.
[68] National Health and Medical Research Council. 2003. *Dietary Guidelines for Australian Adults*. Canberra.
[69] Standard 1.2.8 Clause 17, Australia New Zealand Food Standards Code.

9.3 Structure of the standard

The Australian Food and Grocery Council rejected the positioning of formulated beverage permissions under the non-alcoholic beverages standard. They recommended a new commodity standard under Chapter 2 for 'formulated foods', which has explicit prohibition of additions to alcohol and specifies the maximum levels of total sugar and fat permitted. Water-based flavoured beverages could then form a subcategory of this new standard, along with formulated sports foods, electrolyte drinks and energy drinks.

Response

FSANZ is of the view that a formulated beverages standard is best dealt with under the non-alcoholic beverages standard given that the scope of this Application covers the fortification of non-alcoholic beverages including fruit drinks. Moreover, the current approach is consistent with how other fortified foods are dealt with under the Code and aligns with Ministerial Policy guidelines which state that voluntarily fortified foods be treated as general purpose foods.

9.4 FSANZ's Role in Public Health and Education

Three submitters (two government and one consumer group) considered the Application to be about trade issues, rather than improving public health. In addition a number of submitters noted the issue of consumer education and questioned who should provide and fund this education.

Response

Government as a whole has a responsibility to protect and promote the health and safety of the population. This occurs through the coordinated and inter-sectoral actions of key agencies within the public health system.

Protecting public health and safety refers to the actions taken by society to prevent disease, prolong life and promote health. The Ottawa Charter for Health Promotion (WHO, 1986) identifies a range of personal, social, economic and environmental factors, which can influence the health status of individuals or populations. Access to a safe and nutritious food supply is central to promoting health and wellbeing.

One of the major objectives of developing food regulatory measures is to protect public heath and safety by ensuring that the Australian and New Zealand populations have access to a safe and nutritious food supply. Food regulation can establish wide-ranging parameters applicable at the population level and can support public health interventions. However, food regulation, in itself, is generally not an effective intervention to address public health issues, particularly issues multi-factorial in nature.

FSANZ's primary function is the development, variation and review of food standards. These standards relate to individual foods and food components. While a varied diet contributes to good nutrition, there are many factors which influence food choice. Therefore food standards alone cannot determine an individual's diet and hence dictate an individual's health status.

The FSANZ Act contains three primary objectives that focus the activities of FSANZ on protecting public health and safety, enabling informed consumer choice and preventing misleading and deceptive conduct. The FSANZ Act also establishes goals for FSANZ to achieve which include:

- a high degree of consumer confidence in the food supply;
- an effective, transparent and accountable regulatory framework within which the food industry can work efficiently; and
- the provision of adequate information relating to food to enable consumers to make informed choices.

These and other elements of the FSANZ Act guide the approach taken to the development of food standards and also the role that food standards play in the protection of public health and safety.

Within 'protection of public health and safety' a continuum exists whereby 'safety' frequently refers to single-issue, strongly causally related risks to health whereas 'public health' implies a longer-term, often multi-factorial health outcome. The effectiveness of regulation differs across the continuum, with regulation commonly being more effective when applied to safety risks and much less clear-cut when applied to mitigation of public health risks.

Thus, FSANZ's regulatory approach differs depending on the nature of the risk identified, the strength of the relationship between dietary intake and health outcome, and the level of scientific uncertainty associated with the issue.

Furthermore, FSANZ has a narrow range of tools to use in food regulation. These include unconditional permissions, compositional and/or labelling requirements, and where necessary, prohibition or restriction. In considering the application of these tools, FSANZ adopts a comprehensive risk analysis process which systematically identifies, and determines the most appropriate options for managing any risks using the best available evidence.

While FSANZ's primary objective is the protection of public health and safety, FSANZ must also have regard to its other statutory objectives, for example the promotion of fair trading, the desirability of an efficient and competitive food industry and policy guidelines formulated by the Ministerial Council. Underpinning these considerations is the government requirement for minimum effective regulation.

In addressing broader public health issues, FSANZ seeks to support, strengthen and complement public health initiatives thereby maximising opportunities where possible to protect public health. However, FSANZ's ability to impact on broader health issues is limited. Primarily this occurs by helping to create supportive environments e.g. food labelling to enable consumers to make an informed choice in the context of their individual diet.