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

07/03
15 January 2003

INITIAL ASSESSMENT REPORT

APPLICATION A470

FORMULATED BEVERAGES

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter: **26 February 2003** (See "Invitation for Public Submissions" for details)

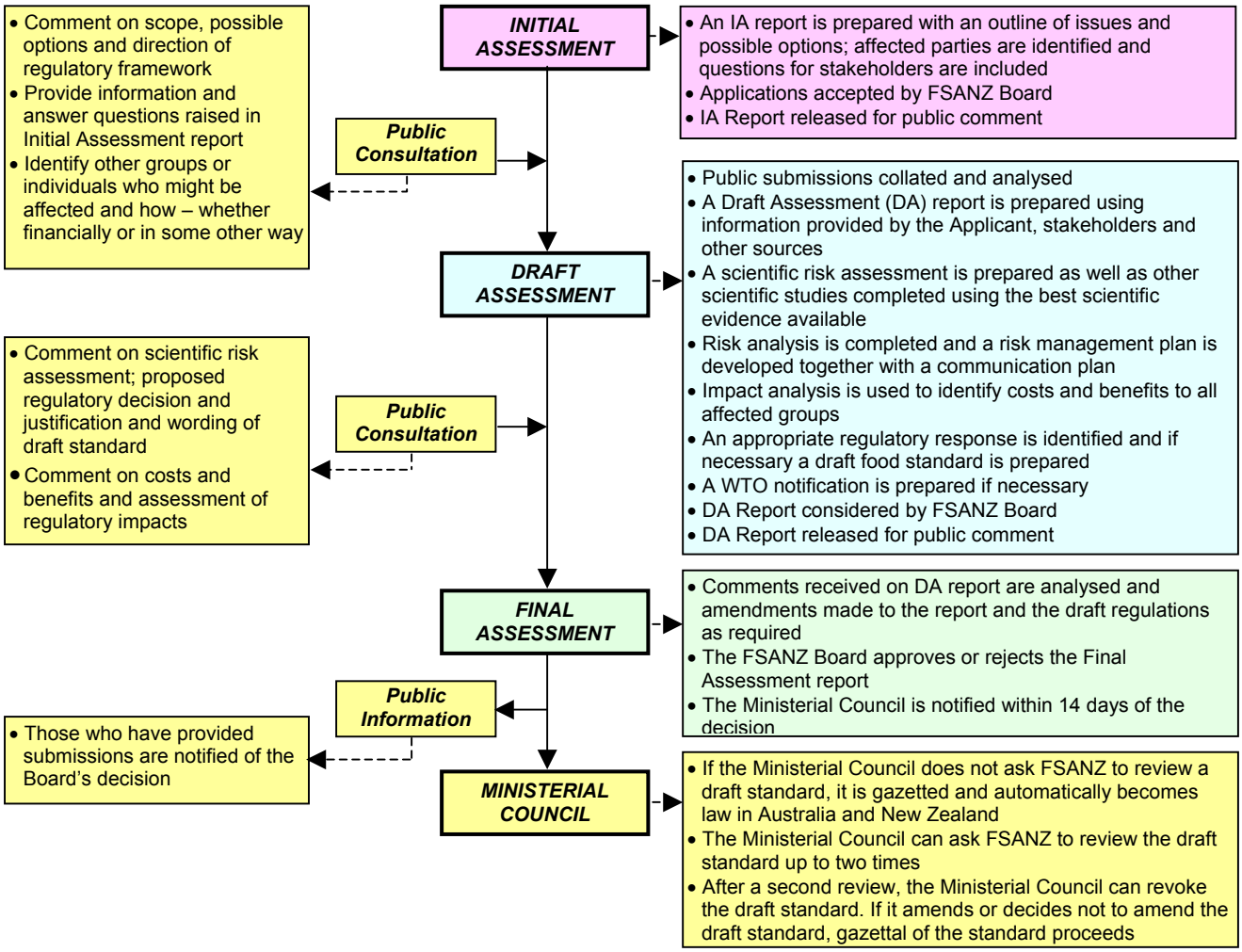
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten governments: the Commonwealth; 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 Commonwealth, 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 Commonwealth, 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 *Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

The Authority has prepared an Initial Assessment Report of Application A470, which includes the identification and discussion of the key issues.

The Authority invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the *Food Standards Code* for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Draft Assessment for this Application. Submissions should, where possible, address the objectives of the Authority as set out in Section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Food Standards Code* (FSC) from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

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

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

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by the Authority **by 26 February 2003**. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

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

CONTENTS

Executive Summary

An Application was received from the Australasian Soft Drinks Association Ltd on 26 June 2002 for the development of a new standard in the *Food Standards Code* (FSC) for Formulated Beverages (FB), described as non-alcoholic water-based beverages containing claimable amounts of a wide range of vitamins and minerals. The vitamins and minerals were requested for addition to FB at levels currently above the permissions for most foods in the FSC. The statutory timeframe for this Application was suspended for 10 weeks as FSANZ sought more information from the Applicant.

The Applicant has requested the creation of a standard for FB as a means of correcting the situation where New Zealand manufacturers can produce these products under the New Zealand *Dietary Supplements Regulations 1985* and sell them in Australia via the *Trans-Tasman Mutual Recognition Arrangement*, while the Australian industry has no such permissions. This Application has been identified as A470 and classified as complexity Category 5 in Group 3 on the FSANZ Workplan, with an initial amount paid by the Applicant to expedite its assessment.

Objectives

The specific objectives of Application A470 are to:

- protect public health and safety through appropriate regulation of FB;
- ensure that consumers can make informed choices about FB; and
- promote fair trade through the development of a consistent and equitable regulatory system for all sections of the FB industry.

Issues

Several issues have been identified as important in meeting the objectives of this Application, and in assessing the regulatory status of FB:

- *The determination of product purpose and definition:*
  In assessing the purpose category for FB, these products can either be classified as general-purpose foods or as having a supplemental purpose similar to food-type dietary supplements (currently under review by Proposal P235) and formulated caffeinated beverages (as regulated by Standard 2.6.4 – Formulated Caffeinated Beverages) in the FSC. Determining which classification is appropriate for FB is fundamental to this Application, as it will determine the presentation of such products, the appropriate regulatory controls, and how FB should be defined.

- *The use of consumption data in the assessment of FB:*
  Accurate data on consumption of FB will enable FSANZ to conduct a risk assessment that is specific to the consumption patterns of FB within the population. At present, the Applicant has provided New Zealand per capita information on the consumption of FB. Without more specific information however, FSANZ will adopt a highly conservative risk assessment during draft assessment of this Application.

- *An appropriate composition of vitamins, minerals, and food additives:*
  The request by the Applicant for vitamin and mineral additions, and the use of specific food additives for FB raises the issue of the appropriateness and suitability of these substances in the context of risk.

  Included within the discussions on composition are: the use of one-day quantities, the nutritional quality of the beverage vehicle, and the use of FB as ingredients in other foods. Discussions on these specific issues will influence the final regulations that are applied to FB. Consideration of medicinal herbs is being undertaken in related proposals, P235 – Food-type Dietary Supplements and P260 – Medicinal Herbs

- *Labelling:*
  Labelling issues are a central consideration for this Application, the foremost being the issue of nutrition claims. The Applicant has requested the ability to claim the vitamin and mineral content of FB. With the requested higher level of vitamin and mineral content, such claims may be considered misleading without further consideration of the nutritional quality of the beverage vehicle. An extension of the claims issue is whether the use of percentage daily intake information such as percentage Recommended Dietary Intake (% RDI) is an appropriate labelling measure when such information may result in declaration of up to multiples of the RDI.

  Other labelling issues discussed in this Report include the use of a mandatory statement advising the maximum one-day quantity of a formulated beverage, and whether a prescribed name is appropriate for the identification of FB.

Regulatory Options and Impact Analysis

There are two options for progressing Application A470 at Initial Assessment:

1. Maintain the status quo, or

2. Include regulations specific to FB in the *Food Standards Code.*

For each regulatory option, an impact analysis has been undertaken to assess the potential costs and benefits to various stakeholder groups associated with its implementation.

Conclusion

For both the Issues and Impact Analysis sections in this Report, a number of questions have been posed to facilitate consideration of this Application. Public comment is invited on these questions, the proposed regulatory options, and the Report as a whole.

Subject to further payment being received from the Applicant to continue this assessment, all responses received by FSANZ will be used to inform the next stage of this Application, including the conduct of any risk assessments and the development of any necessary drafting amendments to the FSC.

1. Introduction

An Application was received from the Australasian Soft Drinks Association Ltd. (ASDA) on 26 June 2002 for the development of a new standard in the *Food Standards Code* (FSC) for Formulated Beverages (FB), described as non-alcoholic water-based beverages containing claimable amounts of a wide range of vitamins and minerals. Permissions for a range of food additives and for the use of some fruit based ingredients, sugars and carbon dioxide were sought. Unlike the currently regulated category of beverages in Standard 2.6.4 – Formulated Caffeinated Beverages, it is proposed that FB will not contain caffeine. The statutory timeframe for this Application was suspended for 10 weeks as FSANZ sought more information from the Applicant.

Because FB can be manufactured in New Zealand under the New Zealand *Dietary Supplements Regulations 1985* (NZDSR), this Application is considered to cover the assessment of the beverage component of the broader proposal, P235 – Food-Type Dietary Supplements, currently at Draft Assessment. This Application has been identified as A470 and classified in Group 3 on the FSANZ Workplan, with an initial amount paid by the Applicant to expedite its assessment.

2. Regulatory Problem

Australian beverage manufacturers are denied the opportunity to manufacture FB whereas these products can be lawfully manufactured in New Zealand under the NZDSR. New Zealand manufacturers are able to produce FB and sell them in Australia in accordance with the *Trans Tasman Mutual Recognition Arrangement* (TTMRA), or to export to third countries, particularly in the Asian region. This system contributes to an uneven playing field and acts against the intent to create a harmonised set of food regulations in Australia and New Zealand.

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives that are set out in section 10 of the *Food Standards Australia New Zealand Act 1991*. 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 Australia and New Zealand Food Regulation Ministerial Council.

The specific objectives of A470 are to:

- protect public health and safety through appropriate regulation of FB;
- ensure that consumers can make informed choices about FB; and
- promote fair trade through the development of a consistent and equitable regulatory system for all sections of the FB industry.

4. Background

4.1 Related Standards in the Food Standards Code

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

The most relevant regulations in Chapter 1 are:
- Standard 1.3.1 – Food Additives; and
- Standard 1.3.2 – Vitamins and Minerals, which permits the addition of carotenes, vitamin C and folic acid in moderate amounts to water-based beverages that contain at least 25% fruit- or vegetable juice; and the addition of vitamin C in moderate amounts to fruit-based cordials.

The relevant regulations in Chapter 2 are
- Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drink, covering most non-alcoholic water-based beverages; and
- Standard 2.6.4 – Formulated Caffeinated Beverages. Many of the provisions contained in this Standard are applicable to an assessment of FB, including the permissions to add vitamins and minerals and the use of some specific labelling strategies.

4.2 Food-Type Dietary Supplements (Proposal P235)

Prior to receipt of this Application, FB were considered within the scope of Proposal P235 – Food-Type Dietary Supplements (FTDS). This Proposal has been prepared to develop regulations in Australia and New Zealand in recognition of the growing market of foods containing added substances with health-related properties. FTDS often contain substances such as vitamins, minerals, non-culinary herbs and other extracts where the presence or amounts are beyond the current permissions in the FSC, but are permitted under the NZDSR. Depending on the defined scope of a formulated beverage, this Application may not consider all beverages that could be considered by P235.

The P235 Initial Assessment Report[1] (containing an appended copy of the NZDSR) was previously released for public comment on 26 June 2002.

[1] http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp235reviewoffoodtypedietarysupplements/index.cfm

4.3 Overseas Regulation of Formulated Beverages

Although FB can be defined as *dietary supplements* under the NZDSR, the regulation of these products, where permitted in overseas jurisdictions, occurs under general provisions for the addition of vitamins and minerals to *foods*. No overseas regulation pertaining specifically to FB has been identified, although the Applicant advises that many countries, including a number of countries in Asia, allow for the production of vitamin and mineral enhanced beverages. Other than its *General Principles for the Addition of Essential Nutrients to Foods*, Codex has no specific measure that addresses FB.

Where they exist internationally, dietary supplements regulations refer to complementary medicines/therapeutic-type dietary supplements (e.g. tablets, capsules etc.), rather than beverages.

Sales of FB, FCB and other 'fortified' beverages in the United States (US), one of the most established overseas markets, have experienced a growth from a niche market of $US500 million in 1996 to an estimated size of $US8 billion today. The majority of this growth has been attributed to energy drinks and vitamin-enhanced beverages.

5. Relevant Issues

Several issues pertinent to the assessment of FB regulation have been identified: determination of product purpose and definition; the use of consumption data to assess the risk of FB; appropriate composition of vitamins, minerals, and food additives; and appropriate risk management strategies including labelling. Where relevant, the precedents and issues established by Standard 2.6.4 – Formulated Caffeinated Beverages and P235 – Food-Type Dietary Supplements have been evaluated to inform the initial assessment of this Application.

5.1 The Characteristics of Formulated Beverages

5.1.1 Purpose

Determination of the appropriate purpose category for FB is fundamental to the assessment of this Application as it will direct the appropriate regulatory approach. The Applicant does not ascribe any particular purpose to FB other than to respond to consumer demand.

The high-level purpose of foods is one of the concepts underpinning the FSC that is particularly pertinent to decisions on the addition of vitamins and minerals to foods (see Attachment 2 for a summary of FSANZ *Regulatory Principles for the Addition of Vitamins and Minerals to Foods* that have been applied to date).

Historically, only two broad categories of purpose were recognised:

- General-purpose foods, ie foods that are widely available for consumption by the general community (the vast majority of foods); and
- Special-purpose foods, ie foods that are produced to satisfy particular dietary requirements which exist because of a particular physical or physiological need, and/or specific diseases and disorders (Part 2.9 of FSC).

A third purpose category for 'supplemental' foods falling outside the conventional nutritional paradigm was created during development of Standard 2.6.4 – Formulated Caffeinated Beverages. Table 1 shows the classification of foods, together with examples, according to high-level purpose within the food/medicine continuum.

Table 1: Classification of foods according to high-level purpose within the food/medicine continuum

Foods			Medicines	
General-Purpose	**Special-Purpose**	**'Supplemental' Purpose**		
• Soft drinks • Fruit & vegetables • Bread • Edible oils	• Infant formula products • Food for Infants • Formulated supplementary sports foods • Foods for special medical purposes	• Formulated caffeinated beverages	• Complementary Medicines/ Therapeutic-type dietary supplements (eg vitamin and/or mineral capsules)	• Other medicines (Over the counter; by prescription)

The purpose category appropriate to FB will need to be determined. The Applicant, while not proposing FB are special purpose foods, is seeking the same vitamin and mineral permissions as currently granted for the special purpose food regulated by Standard 2.9.4 – Formulated Supplementary Sports Foods. For example, magnesium and vitamin E are requested to 50% Recommended Dietary Intake (RDI) per one-day quantity of the product, whereas thiamin and vitamin B_{12} are requested to 200% RDI per one-day quantity of the product. Providing a one-day quantity corresponds to only one or two serves, such permissions generally exceed those permitted in general-purpose foods for the particular vitamin or mineral (restricted to a maximum 25%-50% RDI per reference quantity or serve).

The most likely categories for FB are general purpose or 'supplemental' purpose. Special-purpose foods, (ie foods that are produced to satisfy particular dietary requirements which exist because of a particular physical or physiological need, and/or specific diseases and disorders), are not considered to be appropriate for FB because to date, they have not been positioned in the market to address situations of particular physiological need. If FB were considered to be general-purpose foods, any resultant permission for vitamin and mineral addition would be incorporated into Standard 1.3.2 – Vitamins and Minerals. Alternatively, if FB were considered to be fulfilling a supplemental purpose, then a separate standard would be the appropriate regulatory approach.

General Purpose?

The current FSANZ Regulatory Principles cater for vitamin and mineral addition to foods according to one of three reasons (see Attachment 2 for further detail):
1. Modified Restoration to pre-processed levels,
2. Nutritional Equivalence of substitute foods, or
3. Fortification to address public health need (voluntary or mandatory).

The principles of Modified Restoration and Nutritional Equivalence have limited or no relevance respectively when applied to water-based beverages. For example, Standard 1.3.2

– Vitamins and Minerals already permits fruit drinks and cordials comprising at least 25% fruit juice to contain the small number of eligible vitamins permitted addition according to Modified Restoration. Furthermore, only a few vitamins or minerals sought by the Applicant would qualify under the principle of Voluntary Fortification, for to do so requires a minimum proportion of a described population to have an inadequate intake of that vitamin or mineral. A preliminary analysis of data from national Australian and New Zealand nutrition surveys indicates that only few vitamins and minerals: iron, magnesium, vitamin B6 (New Zealand data only), and calcium could be eligible for consideration on this basis.

Supplemental purpose?

None of the above options for general-purpose foods is likely to deliver, in a timely way and subject to risk assessment, the full scope of the Applicant's request. The third category of 'supplemental' foods may therefore offer the most potential. In adopting such an approach however, the purpose of FB would need to align with the purpose of FTDS. This is consistent with FSANZ's original intention to consider FB within the scope of P235 – Food-Type Dietary Supplements. The P235 Initial Assessment Report provided a discussion of the possible purpose of FTDS as beyond the conventional nutritional paradigm and referred also to functional foods that are generally described as '*providing health benefits beyond simple nutrition*'. If a supplemental purpose were established for FTDS, further elaboration of FSANZ's Regulatory Principles would be required for this third purpose category, building on the elementary framework so far developed from consideration of Standard 2.6.4 – Formulated Caffeinated Beverages and including complementary risk management strategies.

5.1.2 Definitions

Definitions are used within the FSC to separate and identify various types of food, and to assist in the appropriate application of regulatory controls to the foods so defined.

Many definitions in the commodity standards refer to the identity or essential characteristics of the food in terms of ingredient or constituent composition, and may also include reference to a production process. For example, a brewed soft drink is defined in Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft drinks as a '*product prepared by a fermentation process from water with fruit and/or vegetable extractives or fruit and/or vegetable infusions, and sugar'*. Conversely, definitions for special-purpose foods focus either entirely on the purpose of the food or combine elements of composition and purpose. For example, a Formulated Supplementary Food is defined in Standard 2.9.3 as **'***...a food or mixture of foods specifically designed as a supplement to a normal diet to address situations where intakes of energy and nutrients may not be adequate to meet an individual's requirements'*.

It is likely that a definition for FB will need to be formulated irrespective of the purpose category that is determined. The definition of FB therefore may refer to elements of composition and/or purpose. Such a definition will be a key aspect of any future regulation of FB to ensure that the category of FB is unambiguously described and does not inadvertently act as a means to circumvent other, more appropriate food standards.

Submitters are invited to comment on the characteristics of FB (section 5.1) and the following questions:

- Should FB be considered as general-purpose foods?

- Should FB be classified other than as general-purpose foods? If so, what purpose should be ascribed to these products?

- How should FB be defined within the FSC?
  - Is either composition or purpose a defining feature of FB?
  - What range of 'non-alcoholic water-based' beverage products should a definition of FB encompass?

5.2 Consumption of Formulated Beverages

Data on the consumption of the proposed type of food are important to the assessment of the risk associated with the proposed addition of vitamins and minerals or with the requested maximum levels for the use of certain food additives. Such data will determine whether current consumption patterns expose the population, or sections thereof, to an excessive intake of added substances.

Within Australia, there is no method for directly gauging the potential consumption of FB since only small quantities of imported beverages are currently available for sale. Established markets overseas or in New Zealand may be more applicable. The Applicant has indicated that consumption data for FB are not readily available from government agencies and cannot be differentiated from the broader data collected by beverage industries. Nevertheless, the Applicant was able to provide information on the New Zealand per capita consumption of 140mL and 390mL per person per year derived from the sale in 2000-2001 and 2001-2002 respectively of vitamin-added water-based beverages.

Informal observation of the FB market in New Zealand indicates that 400mL bottles are a common individual package size, however information as to the 'recommended daily dose' (as required by the NZDSR) is not always apparent on the label. In the case of Standard 2.6.4 – Formulated Caffeinated Beverages, an average consumption of 500mL per person per day was attributed to FCB. This volume, based on 1999 European data for regular FCB consumers who represented 9% of the European population, was then conservatively applied to all those in the Australia New Zealand target group aged 18-34 years.

Without more specific information on the patterns of consumption of FB especially for those subgroups of the population that are potentially at greater risk such as the elderly, pregnant women and children/adolescents, FSANZ will again adopt a highly conservative approach to risk assessment for this Application. With limited data, a population-wide exposure to an probable overestimate of FB consumption such as 400mL (a bottle a day) would be necessary to ensure the risks to public health and safety have been adequately assessed. However, more accurate and extensive information on consumption patterns would enable the conduct of a more accurate risk assessment that is specific to the likely consumption of FB.

Submitters are invited to comment on the consumption of FB (section 5.2) and the following questions:

- Are you aware of any additional, or more specific data on the consumption of FB in Australia and/or New Zealand than per capita consumption?
- Are you aware of any other data regarding the consumption of FB in New Zealand or overseas markets?
- What do you consider to be the target consumer group for FB?

5.3 Composition

5.3.1 Vitamin and Mineral Addition, and Use of Medicinal Herbs

The regulatory controls applied to vitamin and mineral addition will be determined by the decision on the appropriate purpose category for FB as discussed in Section 5.1. If FB were to be classified as a general-purpose food, and thus the current Regulatory Principles applied, they might qualify for a few permissions under the fortification principle (see Section 5.1.1). Consideration would therefore be given to the potential effectiveness of FB to address dietary inadequacy, as well as to the safety of the proposed vitamin and mineral additions for target and non-target groups alike. The A424 Draft Assessment Report[2] provides an example of the assessment procedures used in accordance with the voluntary fortification principle. Were FB to be regarded as having a supplementary purpose however, the risk of excess consumption of the individual vitamin or mineral would become the prime consideration.

For general-purpose foods, minimum and maximum parameters are established mostly through the use of minimum and maximum claims, respectively 10% RDI/serve and up to 50% RDI/serve. Absolute maximum amounts are also established for those few vitamins and minerals that confer a greater risk.

In the case of FCB, regarded as a 'supplemental' food in relation to vitamins and minerals, maximum limits greater than those permitted for general-purpose foods were established for a small range of vitamins and expressed as absolute amounts per one-day quantity (see Section 5.3.3). These more liberal permissions were complemented by additional risk management strategies (see Section 5.5).

A risk assessment of any proposed levels of vitamin and mineral addition to FB will be conducted during draft assessment after consumption patterns have been established.

Medicinal herbs

Although no mention was made of medicinal herbs in the Application, FSANZ is aware of the use of some medicinal herbs in New Zealand dietary supplement beverages. The

[2] http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa424calciuminjuices/index.cfm .

regulation of medicinal herbs will not be considered within the scope of this Application, however it is being addressed under the companion P235 – Food-type Dietary Supplements, and Proposal P260 – Medicinal Herbs.

5.3.2 Composition of the Beverage Vehicle

The Applicant has referred to the type of beverages covered by this Application as 'water-based beverages' and sought permission for the use of sugars, carbon dioxide and certain fruit-based ingredients. 'Water-based beverages' is not currently defined in Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drink but its broad composition can be inferred from the context of that Standard to include products whose ingredient composition ranges from mostly water to, for example, those fruit drinks (defined as containing at least 5% specified fruit ingredients) containing mostly juice with a small amount of added water. The potential overlap with general-purpose fruit drinks containing at least 25% fruit ingredients that are permitted to contain a small number of added vitamins by Standard 1.3.2 – Vitamins and Minerals according to the modified restoration principle would need to be borne in mind. Consideration would need to be given to whether a broad compositional range was appropriate for FB or whether these beverages should be confined to lower amounts of fruit-based ingredients than either 25% fruit drinks, or even the fruit drink category itself (minimum 5% fruit).

A corollary to the decision about the appropriate purpose category for FB is level of regulatory control, if any, required over the nutritional quality of the beverage vehicle - the non-alcoholic water-based beverage. The Applicant has sought permission for FB to carry vitamin and mineral content claims to the level of 'good source' and thus enable these products to be promoted and potentially regarded by consumers as a nutritious product. From a regulatory perspective, the beverage vehicle could be considered either as a mere carrier of the added vitamins and minerals such that the composition of the beverage is incidental and of no regulatory interest; or as an enhanced substitute for either an unfortified or less fortified counterpart or other more nutritious beverage, for example, in the extreme case of calcium-fortified soft drink for milk. If the latter, the impact of FB consumption on dietary intakes of nutrients other than vitamins and minerals becomes important, particularly for nutrients that are the subject of authoritative dietary guidance. In this case, some regulatory intervention such as limiting the amount of added sugars in FB might be considered.

5.3.3 One-Day Quantity

The Applicant proposed the addition of vitamin and minerals to FB as per 'daily dose'. The FSC, however, expresses such permissions as 'one-day' rather than 'daily' quantities, as the former is interpreted to mean the full amount over any one day whereas the latter refers to the amount that can be habitually consumed each day. The term 'dose' is inappropriate for use in food regulation (see Section 5.5.3); instead, food amounts are described in terms of either a specified reference quantity; or as a one-day quantity or serve as determined by the manufacturer.

Although 'one-day quantity' has seldom been used in the FSC as reference amounts for foods permitted to contain added vitamins and minerals, its use confers benefits to both consumers and manufacturers in cases where higher amounts of vitamins and minerals are permitted:

- consumers are protected because of the upper limit established for the amount of vitamins and minerals consumed from a labelled one-day quantity of the product such that the higher the concentration of vitamin or mineral, the smaller the one-day quantity; and
- manufacturers are provided with the flexibility to determine within an upper limit, the concentration of a vitamin or mineral in concert with the one-day quantity to be advised on the label. The system is more flexible than the generic Standard 1.3.2 where permissions are expressed per fixed reference quantity.

Examples of the use of one-day quantities are given in Standard 2.6.4 – Formulated Caffeinated Beverages and Standard 2.9.4 – Formulated Supplementary Sports Foods.

5.3.4 The Use of Formulated Beverages as Ingredients in Other Foods

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

The possible carry-over of vitamins and minerals from FB to mixed foods or beverages that are not subject to the risk management labelling controls applicable to the original product, such as mandatory advisory statements, potentially leaves consumers exposed to risk. Although Standard 1.3.2 – Vitamins and Minerals restricts to some extent the foods permitted to carry vitamin and mineral claims, the definition of such 'claimable foods' theoretically allows for the inclusion of a widely-fortified FB ingredient. An allowance for carry-over could potentially offer opportunities for manufacturers to circumvent the spirit of the Regulatory Principles governing the addition of vitamins and minerals to the general food supply.

Submitters are invited to comment on the composition of FB (section 5.3) and the following questions:

- Are you aware of any safety concerns from an implementation of the Applicant's proposed maximum levels for the addition of vitamins and minerals to FB (refer to Attachment 1 for more detail)?

Please supply evidence in support of your position including:

- identification of those groups within the population that you believe might be at risk of consuming excess amounts of vitamins and minerals; and
- any known adverse health effects that might result from the proposed addition of vitamins and minerals to FB, and the level of formulated beverage consumption at which these effects might occur.

- Is the range of vitamins and minerals proposed for addition to FB appropriate? Should certain vitamins and minerals be excluded from any FB permissions?

- Should FB regulations address the nutritional quality of the base beverage?
  - Does the base beverage act only as a carrier for the added vitamins and minerals, or does it have a more significant role in the diet?
  - How are FB used by consumers?
- Is one-day quantity an appropriate basis for the regulation of FB vitamin and mineral content?

- Should the use of FB as ingredients in other foods be prohibited? If not, what might be the flow-on effects of such use?

5.4 Food Additives

The use of food additives is regulated by Standard 1.3.1 – Food Additives, and particularly Schedules 1 to 5. Schedule 1 of this Standard permits the use of food additives in specific foods. Maximum permitted levels are prescribed for additives where dietary exposure 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. Schedule 4 list colours that are generally restricted to 290 mg/kg for solid foods and 70 mg/kg for liquids and which may be further restricted by Schedule 1. Schedule 5 lists the permitted technological functions to be performed by food additives as distinct from processing aids (Standard 1.3.3) and vitamins and minerals (Standard 1.3.2).

The Applicant has requested permission for use of a wide range of food additives in FB. Some of these requests are in accordance with GMP and are therefore covered by the permissions in Schedules 2 and 3 of Standard 1.3.1 whereas colours have been requested for use in accordance with Schedule 4. The majority of levels requested for other additives, although outside the requirements of GMP, are compliant with the permissions currently available for non-alcoholic beverages in Schedule 1 under the headings of '14.1.2.2 – Fruit and vegetable juice products' and '14.1.3 – Water-based flavoured drinks'. The maximum permitted levels of these food additives in FB needs to be consistent with the technological

need used to justify their use in beverages of similar composition. A safety assessment may be necessary for the requested maximum limits that occur outside of GMP permissions in the FSC, should it be determined that the limits for other non-alcoholic water-based beverages are not applicable to FB.

A risk assessment of the proposed levels of food additives from FB will be conducted during draft assessment after the establishment of consumption patterns.

A list of the requested maximum levels of food additives in FB is given at Attachment 1.

Submitters are invited to comment on the use of food additives in FB (section 5.2) and the following questions:

- Are the proposed maximum levels for the use of food additives in FB appropriate? Are there any safety concerns associated with the range of food additives proposed?
- Are the proposed food additives suitable for the types of foods covered by the scope of this Application? Are these additives essential for the manufacture of FB?
- Are you aware of any data that would be relevant for a safety assessment on the use of food additives in FB?

5.5 Labelling

Labelling is regulated in the FSC 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.

5.5.1 Nutrition Claims

The Applicant has requested that FB be permitted to carry claims of 'source' or 'good source' for the vitamin and mineral content. Nutrition claims, that is, those that relate to content and function, are permitted under Standard 1.3.2 – Vitamins and Minerals for general-purpose foods providing a vitamin or mineral is listed in the Schedule to Standard 1.1.1 – Preliminary Provisions; and is present in a 'claimable food' in amounts of no less than 10% RDI per serve for a 'source' claim, or no less than 25% RDI per serve for 'good source' claim, but in both cases less than the maximum claimable amount. A 'claimable food' is one that has at least a moderate nutritional quality. Also, a voluntary declaration of the vitamin or mineral content on a label including in a Nutrition Information Panel (NIP) also constitutes a nutrition claim and is subject to the above conditions.

If FB were considered to serve a supplemental purpose, it is likely that a product's vitamin and/or mineral content would be a key feature. Although a manufacturer's ability to promote the vitamin and mineral content of FBs is consistent with a supplemental purpose, such claims could confer a nutritional or 'healthy' status on the product that may not have been warranted for the unfortified counterpart. Permission for nutrition claims should be considered together with a consideration of the nutritional quality of the beverage vehicle to

determine whether such claims would be permitted only on beverages of a minimum nutritional quality.

5.5.2 Percentage Daily Intake Information

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

Previous considerations of FCB raised similar concerns where vitamin additions were permitted in higher amounts than for other foods. During the development of Standard 2.6.4 – Formulated Caffeinated Beverages, it was considered that the display of percentage daily value information calculated from reference values based on estimates of dietary adequacy such as the RDI was inappropriate for formulated caffeinated beverages (FCB) and that only quantitative declarations per serve should be permitted.

As FB may be permitted to contain a wide range of vitamins and minerals at high levels, it could be argued that similar to FCB and to the current labelling requirements in the NZDSR, FB should be permitted to declare only quantitative amounts of vitamins and minerals present in the beverage.

5.5.3 Mandatory Statements

In addition to the possible use of one-day quantities as a means of regulating vitamin and mineral composition of FB, as requested by the Applicant, there may be a need to mandate additional label information to manage risk. Where one-day quantities are used in the FSC, there is a concomitant requirement for the one-day quantity to be stated on the label. The wording of such a statement varies but for FCB the statement is "*consume no more than [amount of one day quantity (as cans, bottles or mL)] per day*". Other advisory statements are also required that identify the population groups for which FCB are not recommended such as children, pregnant or lactating women, and individuals sensitive to caffeine.

Some public health and government submitters to the Initial Assessment Report for P235 also suggested that other labelling statements were warranted, such as 'this food is a [food type dietary supplement] and should not replace a healthy balanced diet', or 'FTDS are not assessed and approved by regulatory authorities as providing health benefits'.

During the development of Standard 2.6.4 – Formulated Caffeinated Beverages, it was concluded that the term 'dosage' should not be used on a label to describe the recommended number of serves, as is currently required in the NZDSR. Such a term was viewed as implying that a certain amount should be consumed in a day, which was contrary to the labelling requirement indicating the maximum amount that should not be exceeded.

5.5.4 Prescribed Name

The Applicant has requested that the term 'formulated beverages' not be made a prescribed name. Prescribed names are provided in the FSC primarily for use by enforcement agencies in the identification and regulatory classification of foods. Without a prescribed name, the generic provisions in Standard 1.2.2 – Food Identification Requirements that require a label to contain *"...a name or description of the food sufficient to indicate the true nature of the food*" would apply to FB. The presentation of FB would need to be readily distinguished from other food categories for a prescribed name not to be required. This could be achieved if unique mandatory statements were required.

A prescribed name was initially proposed for FCB during the development of Standard 2.6.4 – Formulated Caffeinated Beverages. However, this requirement was eventually omitted from the final standard as it was concluded that the product could be identified for enforcement purposes through the other unique labelling requirements such as quantitative caffeine declaration, and also that a prescribed name could constitute a potential barrier to trade, was long and unwieldy, and could easily be covered by the generic naming requirements in Standard 1.2.2 – Food Identification Requirements.

Submitters are invited to comment on labelling issues (section 5.5) and the following questions:

- Should FB regulations restrict the labelling of vitamin and mineral claims?
  - If so, which ones?
  - Should restrictions be placed on some types of claim (e.g. limited to content claims only), or should all claims for vitamins and minerals be prohibited?

- What do you view as the positive and negative aspects of labelling with percentage daily intake information on FB?
  - Should information on the vitamin and mineral content of a formulated beverage be displayed in quantitative terms only? If so, should this information be made mandatory?

- Is the statement "*consume no more than [amount of one day quantity (as cans, bottles or mL)] per day*" an appropriate means of managing the risk associated with the use of one-day quantities? If not, what alternate statements or methods could be used to manage this risk?

- Do the generic naming provisions in Standard 1.2.2 adequately allow for the identification of FB? Would a formulated beverage be readily identifiable from other food categories without a prescribed name?

- Should FB be labelled with statements that advise against regarding FB as substitutes for a healthy diet, or as providing health benefits?

6. Regulatory Options

There are two options for progressing A470 at Initial Assessment:

1. *Maintain Status Quo*

To maintain the *status quo* by not including a set of regulations for FB in the FSC, or by providing a set of permissions for the proposed addition of vitamins and minerals to non-alcoholic water-based beverages.

2. Include Regulations Specific to Formulated Beverages in the Food Standards Code

Under this option, specific provisions on the addition of vitamins and minerals, use of food additives, and labelling requirements would be provided within the appropriate section(s) of the FSC for FB. Consistency with other related areas in the FSC and with overseas FB regulations would be particularly considered in this option.

7. Impact Analysis

7.1 Affected Parties

The parties affected by this proposal are: **consumers** including adolescents and young children; Australian and New Zealand importers and manufacturers of FB who make up the FB **industry**; and the **governments** of New Zealand, Australian States and Territories, and the Commonwealth of Australia.

7.2 Cost-Benefit Assessment of the Regulatory Options

This analysis assesses the immediate and tangible impacts of current food standards under Option 1, and the potential for growth in market for FB under Option 2.

In this analysis, the formulated beverage market excludes sports drinks and FCB, for which permissions exist under current food standards.

7.2.1 Option 1 – Status Quo

Consumers

In New Zealand, the FSC does not affect the range of FB available to consumers because these products are permitted for sale - from local production or imports - under the NZDSR. Consumers are able to exercise choice, and hence benefit from these arrangements.

In Australia, the FSC does not allow the supply of FB to the domestic market, from local production or imports. However, New Zealand imports are a special case, and imports of FB are allowed onto the Australian market under the TTMRA. FB are thus available to Australian consumers, although the range of products might be less than that available to New Zealand consumers. The restriction of the current regulatory environment that prevents Australian industry from manufacturing these products is unlikely to be perceived by Australian consumers, and hence they would be equally unaware of any limitation on the potential range of products that could become available.

- Do you have any information on the range of formulated beverage products available in Australia and in New Zealand?

- Do you have any information on how consumers perceive FB? Do people consume FB for the vitamin and mineral content, or more as an alternative to other beverages?

- As a consequence of consumer perceptions, could there be a significant substitution of FB for particular products?

The consumption of FB by consumers outside the target market (e.g. children) may have a potential for harm. However, at present, there is no information to suggest any possible harm from such unintended consumption.

- Do you have any information on the consumption of FB by consumers outside the target market?

Industry

The scale of the impact of current food standards on industry would be small, as the size of the market for FB is expected to be small (sports drinks and FCB are not included in this market segment).

However, the regional impacts of the current regulatory arrangements are very different: an opportunity cost to the Australian industry and a benefit to the New Zealand industry. New Zealand industry is allowed to manufacture FB under the NZDSR, and in addition it can export these products to Australia under the TTMRA. This is a significant benefit to the New Zealand industry. Australian industry cannot compete in this market segment, being prevented by a lack of permission to do so under the current provisions of the FSC.

Overall, while the costs incurred by Australian industry appear to be balanced by benefits to New Zealand industry, the marked contrast in regional impacts is inequitable and undesirable.

- Do you have any information on the size of the market for FB in Australia and/or New Zealand, how each market has grown in recent years, or comparative data on the related products of sports drinks and FCB?

- Regarding the New Zealand market for FB, to what extent is it supplied by domestic production and imports? Do you have comparative data for the related products of sports drinks and FCB?

- Regarding the Australian market for FB, to what extent is it supplied by New Zealand production, and imports from other countries (other countries can supply the Australian market by "re-exporting" via New Zealand under the TTMRA)? Do you have comparative data for the related products of sports drinks and FCB?

- Do you have information on industry structure: the number of FB producers in New Zealand, percentage of production accounted for by the largest companies; and equivalent information for Australian industry in terms of potential entrants into this market? How competitive is/will the market be for FB?

Government Enforcement Agencies

There is a potential cost of enforcing food standards in Australia, in resolving a potentially confusing situation where the FSC does not permit FB for sale even though such products remain lawfully available under the TTMRA.

- Is this a significant issue / priority for enforcement agencies?

7.2.2 Option 2 – Inclusion of Regulations Specific to Formulated Beverages in the Food Standards Code

Australian Consumers

The immediate impact of allowing industry to produce FB would be to increase the range and availability of these products for consumers. This is a benefit, although a small one.

For the future, the Applicant has high expectations of the Australian market reaching a potential level equivalent to US consumption. If true, Australian consumers will benefit substantially from exercising choice. If the market expands to a lesser degree, there will still be significant benefits to Australian consumers.

- The Applicant has claimed that the market for FB has the potential to reach the level reached in the US, on a per capita basis. How reasonable is this claim in the light of the experience in other overseas countries that consume FB?

While there is no information, at present, to suggest any possible harm from unintended consumption of FB, any expansion of this market may introduce new risks.

- Do you have any information to suggest risks of unintended consumption, as the range of formulated beverage products increases or as FB become available in greater volume?

New Zealand Consumers

New Zealand consumers are unlikely to notice any particular change under Option 2. FB are already available in New Zealand, from local production and imports. In the long-term, the range of products available may be expanded by exports from Australia, although the Australian industry appears to be focused more on Asia than New Zealand.

Australian Industry

Australian industry will benefit immediately under this option, in being able to produce FB for the current Australian market. Although the current market is small, this is a discernible benefit.

Australian industry will also benefit from growth in the Australian market for FB. The Applicant claims the potential market is huge. By including FB together with sports drinks and FCB – an "all fortified soft drinks market" – the Applicant claims that Australian consumption could reach $800 million a year, on the basis of current per capita consumption in the US, as a benchmark. The current market for "all fortified soft drinks" in Australia could be as high as $150 million (an estimate based on incomplete data). To reach the claimed potential within a decade this market will need to expand each year by 20%.

- Long-term growth in the total soft drinks market is about 3.5% per year. A rate of growth for any segment of 20% seems very high, especially when this rapid growth has to be sustained over a long time period. How credible is a 20% yearly growth in the "all fortified soft drinks" market? Can it be sustained for ten years?
- In the past five years, sports drinks and FCB have dominated growth in the "all fortified soft drinks" market. In future years, expansion of this market could be driven by FB. Do you have any information on projected growth of the FB market?
- To what extent will future growth of FB in Australia and New Zealand reflect expansion of current products, or growth in new and innovative products?
- Is US consumption the most relevant benchmark for Australia? Are there any factors that would affect the transferability of the US experience to Australia? What does other overseas experience suggest?

The Australian economy will also benefit from this option. Once industry commences the manufacture of FB, an increase in employment is possible. The Applicant suggests that if production increases to meet the full potential demand, over 1,000 new jobs could be created (obviously the employment effect will be smaller if growth in demand and production are more modest). Option 2 also facilitates exports of FB, with the Applicant identifying Asia as an export market of high potential. However, the cost of transporting beverages is a significant barrier to exports; as an indication, only 5% of Australia's total soft drinks production is exported. It is probable that the Australian industry can export FB, but more to satisfy niche, high value markets rather than high volume markets. The export potential, while it is worthwhile, may not be that significant in relation to Australia's overall export performance.

- Do you have any comments on the capacity of the Australian beverage industry to generate employment?
- Do you have any comments on the export opportunities for FB?

Other industries also benefit when the Australian beverage industry commences production of FB. These are the industries that supply inputs to the manufacture of beverages: producers of packaging, including glass, plastics and aluminium; transport; wholesalers; and retail chains and food service outlets. This effect magnifies the initial boost of the Australian beverage industry to the whole economy.

- Do you have any information to suggest how large the "multiplier" impact might be?

While expansion of the beverage industry will benefit the economy, the extent of the benefit will be ameliorated by a number of factors. Some of the future growth in FB would occur from redistribution between different beverages. FB may take market share away from similar products in the non-beverage markets, such as the dietary supplement market (both food- and therapeutic-type dietary supplements). In the short-term, the overall net gain to the economy as a whole could be modest. In the long-term, it is possible that the accumulation of substitution between industries would mean that resources merely shift from one industry sector to another, and that the economy-wide impact would be neutral.

- Do you have any information on the likely substitution between FB and other beverages?
- Do you have any information on the likely substitution between FB and non-beverage products, such as dietary supplements?
- Are there any more general economic influences that would tend to offset the short-term boost to economic activity, and result in a neutral impact over the long-term?
  - Alternatively, is the initial expansion of economic activity sustainable over the long term?

Overall, Option 2 provides benefits to the Australian soft drinks industry, and possibly to the Australian economy. The size of these benefits will be assessed in the light of further information.

New Zealand Industry

The immediate impact of Option 2 could reduce New Zealand exports of FB to Australia, as the local industry competes in this market segment. This would be a cost; but the extent of the cost would depend on how well the New Zealand brands are established on the Australian market.

Over time, growth in the Australian FB market would drive an expansion of New Zealand exports to Australia. New Zealand would have a share of local production for this market, rather than a monopoly on local production, but in absolute terms would still benefit from growth in production and exports.

- Do you have information on the likely impact from Option 2 on the export of New Zealand FB to Australia that will occur:
  - in the immediate future?
  - over the next 5-10 years?

- Do you have any information of the impact from Option 2 on the export of New Zealand sports drinks and FCB to Australia, where permissions for these products are provided within the FSC?

Industry would have the option of manufacturing under NZDSR or under a new standard of the FSC. This option is not available to Australian industry, and depending on the specifications of any new standard, it may provide a competitive advantage to the New Zealand industry.

Government Enforcement Agencies

Option 2 would remove any uncertainty in the enforcement of the FSC. To the extent this had been a discernible issue requiring real resources to address, enforcement agencies will benefit from greater clarity of regulations.

8. Other Considerations

8.1 Amendments to Complementary Regulations

The ongoing ability to manufacture foods to the NZDSR and import them into Australia has the potential to severely undermine the harmonisation of food standards for both FTDS and FB, and therefore it is important that the progression of A470 be closely linked to any amendments or revocation of the NZDSR and to the progression of P235 – Food-Type Dietary Supplements.

With the commencement of assessment of A470, FB have been separated from the processes and assessments currently taking place under P235. Despite this separation, FB will be subject to the outcomes of P235 that is assessing a number of wider issues related to regulatory framework for FTDS, and the addition of nutritive and other substances to foods beyond current permissions in the FSC. Therefore, the order in which the regulation of all food-type dietary supplements is finalised will be determined by the order in which the 2 companion projects are completed. One or other projects will probably need to include consequential amendments to the FSC to integrate relevant provisions into a consistent framework.

8.2 Workplan Classification

This Application had been provisionally rated as complexity Category 5 and placed in Group 3 on the FSANZ Workplan. This Initial Assessment confirms these ratings. Further details about the Workplan and its classification system are given in *Information for Applicants* at www.foodstandards.gov.au.

8.3 World Trade Organization (WTO)

As members 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.

Amending the *Food Standards Code* to approve a category of FB will remove many of the current regulatory barriers and is likely to facilitate international trade in this category of beverages. Given there are no relevant international standards, but the positive impact on trade may be significant, there may be a need to notify the WTO. This issue will be fully considered at Draft Assessment and, if necessary, notification will be made in accordance with the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements.

9. Consultation

9.1 Stakeholder Forums

Stakeholder forums may be held in both Australia and New Zealand following the review of submissions from the first round of public comment and before the preparation of the next stage of this Application, the Draft Assessment. It more likely however, that any forums would consider A470 and P235 together.

9.2 Release for Public Consultation

The Initial Assessment Report will be released for a six-week consultation period. Subject to further payment by the Applicant and progression of A470 as a Group 3 classification on the FSANZ Workplan, the views expressed in submissions received during this period will be incorporated into the development of a Draft Assessment Report and a second round of public comment will commence following the release of that Report.

10. Conclusion

This Initial Assessment Report discusses specific issues in relation to the creation of a standard for FB as proposed by the Applicant. Included within this Report are a number of questions and two proposed regulatory options for which FSANZ seeks public comment. Subject to further payment by the Applicant, responses to this Report will be used to further assess this Application, including the undertaking of any risk assessments and the development of any necessary drafting amendments to the FSC.

11. Glossary Of Acronyms

A470	Application A470 – Formulated Beverages
ASDA	Australasian Soft Drink Association
FB	Formulated Beverages
FCB	Formulated Caffeinated Beverages
FSANZ	Food Standards Australia New Zealand
FSC	Food Standards Code
FTDS	Food-Type Dietary Supplements
GMP	Good Manufacturing Practice
NIP	Nutrition Information Panel
NZDSR	New Zealand *Dietary Supplements Regulations* 1985
P235	Proposal P235 – Food-Type Dietary Supplements
RDI	Recommended Dietary Intake
TTMRA	Trans Tasman Mutual Recognition Arrangement
US	United States of America

12. Attachments

1. Permissions Requested for Application A470
2. Regulatory Principles for the Addition of Vitamins and Minerals to Foods

Attachment 1

Permissions Requested by Application A470

The Applicant, the Australasian Soft Drink Association (ASDA), has requested the following permissions for inclusion in a new standard for formulated beverages (FB).

Vitamins and Minerals

1. The ability to claim on a label the presence of an added vitamin and mineral through the use of the statements "a source of (vitamin and mineral to be inserted)" or "a good source of (vitamin and mineral to be inserted)".

2. Permission for the addition of vitamins and minerals (based on those given in Standard 2.9.4 - Formulated Supplementary Sports Foods) as follows:

Vitamin / Mineral	Maximum Permitted Amount in a Daily Dose
Vitamin A	375 μg
Thiamin	2.2 mg
Riboflavin	3.4 mg
Niacin	20 mg
Folate	400 μg folic acid
Vitamin B_6	3.2 mg pyridoxine
Vitamin B_{12}	4 μg
Vitamin C	80 mg in total of L-ascorbic acid and dehydroascorbic acid
Vitamin D	2.5 μg
Vitamin E	5 mg alpha-tocopherol equivalents
Biotin	15 μg
Pantothenic Acid	2.5 mg
Calcium	400 mg
Chromium	100 μg (inorganic and organic forms)
Copper	1.5 mg (inorganic and organic forms)
Iodine	7 5μg
Iron	6 mg
Magnesium	160 mg
Manganese	2.5 mg (inorganic and organic forms)
Molybdenum	125 μg (inorganic and organic forms)
Phosphorus	500 mg
Selenium	35 μg (inorganic and organic forms)
Zinc	6 mg

Food Additives

3. The following food additives, including: flavours permitted in Schedule 2, colours permitted in Schedule 3 and 4 of Standard 1.3.1 – Food Additives of the Food Standards Code (FSC); and the following:

Food Additive	Maximum Amount (mg/Kg)
Artificial Sweeteners	
Acesulphame K	300
Alitame	40
Aspartame	GMP
Cyclamate	600
Neotame	GMP
Saccharin	80
Sucralose	GMP
Thaumatin	GMP
Preservatives	
Benzoic acid and benzoates	400
Propionates	GMP
Sorbic Acid and sorbates	400
Sulphur dioxide and sulphates	115
Modifying Agents	
Calcium disodium EDTA	33
Dimethyl dicarbonate	250
Dioctyl sodium sulphosuccinate	10
Glycerol esters of wood rosin	100
Sucrose acetate isobutyrate	200
Colourings	
Amaranth	40
Annatto	10

GMP – Good Manufacturing Practice

Ingredient Composition

4. Permission for FB to contain carbon dioxide and sugars at unspecified amounts.

5. Permission for FB to contain fruit juice, puree concentrates, orange peel extract and/or commercial fruit.

Attachment 2

Regulatory Principles for the Addition of Vitamins and Minerals to Foods Executive Summary

Guiding Statement

Consistent with the Codex *General Principles for the Addition of Essential Nutrients to Foods*, the addition of vitamins and minerals to general-purpose and special-purpose foods should not be permitted where no adequate nutritional rationale can be provided. Regulatory principles that are elaborated in accordance with this guiding statement aim to prevent the indiscriminate addition of essential nutrients to foods thereby reducing the risk of health hazards due to essential nutrient excesses, deficits or imbalances.

Regulatory Principles

General-Purpose Foods

Mandatory Fortification

Mandatory fortification of specific foods or food categories should be implemented where it is scientifically demonstrable that a significant benefit to the health and/or life expectancy of the target group outweighs the risk to other population groups. Also, that the economic savings in the costs of health services and in improved productivity are at least commensurate with the costs imposed on industry.

The following criteria need to be satisfied before mandatory fortification should be instituted.

1. Evidence of a nutritional need as assessed by at least moderate levels (severity, prevalence or both) of subclinical or clinical indicators of a disease of public health significance;
2. At least moderate attribution of inadequate vitamin or mineral intakes to the cause of the disease (including vitamin or mineral deficiency);
3. High probability of improving that disease outcome in target groups via passive consumption of an appropriate efficacious food;
4. Low health risk to non target population groups from mandatorily fortified food;
5. Low risk of excess vitamin or mineral consumption or adverse nutrient interaction for all population groups;
6. Technical feasibility of the nutrient in the chosen food; and
7. Industry capacity to comply within regulatory limits.

Decisions to adopt mandatory fortification would not necessarily require evidence of market failure in relation to a voluntary permission for addition of the vitamin or mineral of interest.

Voluntary Fortification

Specified food categories may be voluntarily fortified with vitamins and minerals to potentially address situations where:

1. There is evidence of dietary inadequacy as assessed by the percentage (generally 30% or more) of the whole population or more than one age/sex subgroup whose customary vitamin or mineral intakes are below the respective (UK) Estimated Average Requirements (EAR). The nutrient of interest may also be related to a disease outcome of public health significance; and
2. The food category proposed for fortification is consistent with nationally endorsed guidance for healthy eating. To avoid the promotion (by virtue of a nutrient content claim) of foods that might increase risk factors for disease if consumed in excess amounts or that have little nutritional value, the following compositional criteria should be applied to candidate foods:
   a) The food category generally must have no more than 25% by ingoing weight of:
      i) added sugars[3]; and
      ii) any ingredient comprising more than 75% triglyceride.
   b) The food category generally must contain no more than 800mg sodium per manufacturer's serve size.
   c) The food category generally, *prior to vitamin and/or mineral addition*, must also naturally contain at least one vitamin or mineral whose content is at least 5% of the Recommended Dietary Intake (RDI) as listed in the Schedule to Standard 1.1.1 per manufacturer's serve size.

Modified Restoration[4]

Vitamins and minerals may be added, subject to no identified risks to public health and safety, at moderate levels (generally 10-25% Recommended Dietary Intake (RDI) per reference quantity) to some basic foods providing that the vitamin or mineral is present in the nutrient profile, prior to processing, for a marker food in the food group to which the basic food belongs. The vitamin or mineral must be naturally present at a level which would contribute at least 5% of the RDI in a reference quantity of the food. This regulatory principle is based on the restoration or higher fortification of the vitamin or mineral to at least pre-processed levels in order to improve the nutritional content of some commonly consumed basic foods.

Nutritional Equivalence

Vitamins and minerals may be added, for the purpose of nutritional equivalence, to specified foods that substitute for certain basic foods.

[3] Defined as: hexose monosaccharides and disaccharides, including dextrose, fructose, sucrose and lactose; or starch hydrosylate; or glucose syrups, maltodextrin and similar products; or products derived at a sugar refinery, including brown sugar and molasses; or icing sugar; or invert sugar; or fruit sugar syrup; or malt or malt extracts; or honey; or concentrated and/or deionised fruit juice.

[4] This Regulatory Principle was modified from the Codex General Principle of restoration

Criteria for Content Claims

In general, claims to the effect that the particular food product is a 'source' or a 'good source' of a vitamin or mineral may be made providing a reference quantity of the food contains at least 10 percent or 25 percent of the RDI respectively for the particular vitamin or mineral and the food is a 'claimable' food[5].

Historical Precedent

Food categories which, historically to 1995, were fortified by a significant proportion of manufacturers, (on the basis of market share) were granted permission to be fortified at moderate levels with those same vitamins and minerals, providing no risks to public health and safety were identified. It is not anticipated that this Regulatory Principle will apply in the future.

Special-Purpose Foods

The definition of special-purpose foods is firmly grounded within a traditional nutrition paradigm that has as its basis, dietary adequacy to support physiological growth, development and maintenance of health. Regulation aims to ensure that such products are effective in achieving their intended purpose and in so doing, mitigates the risk to the target group from consumption of nutritionally inferior products. This generally requires the establishment of minimum vitamin and mineral levels, which could be achieved either through the natural content of the ingredients, or by addition. Other essential vitamins and minerals not permitted in general-purpose foods such as biotin or selenium may also be permitted. Depending on the role of the product, the actual minimum levels should be proportional to the contribution of the food to the energy and macronutrient content of the daily diet. The reference values used to set minimum levels are Australian RDIs and, where needed, those of other overseas countries. Such an approach is consistent with the fourth Codex General Principle that explicitly states the need for such foods to have an appropriate and adequate nutrient content.

Maximum limits are determined in accordance with the purpose of the special-purpose food, and the risk to the target group from consumption of the product. It is recognised that the routine dietary intake assessments undertaken for general-purpose foods, may not be appropriate for this category of foods depending on the consumption of the special-purpose product and of other general-purpose foods.

Supplemental Foods

The term 'supplemental foods' is not officially defined but has been devised to describe a third category of foods that has a 'functional' purpose outside the conventional nutrition paradigm. The elaboration of Regulatory Principles for this category of foods is in its infancy, however to the extent that they were developed for formulated caffeinated beverages, they have been included in this document.

[5] 'Claimable food' is defined in Standard 1.3.2 – Vitamins and Minerals as at least 90% by weight of primary foods, or foods permitted voluntary addition, or a mixture of these (excluding butter, cream, edible oils, edible oil spreads and margarine) and water.

The regulation of formulated caffeinated beverages as an early example of supplemental foods required the formulation of a new approach that took account of the purpose of the food, and which adopted a new range of risk management labelling strategies.

The regulation of vitamins or minerals in supplemental foods so far has been predicated on these micronutrients having a role, however perfunctory, in achieving the function and purpose of the product. The specific levels permitted however were not linked to the achievement of or contribution to product effectiveness. Maximum levels were established per one-day quantity in accordance with the assessed level of risk of excess consumption of that micronutrient from total food, and other forms of supplemental intake, and because dietary surveys often do not include these products, an estimate of the product's one-day level of consumption. No minimum amounts of vitamins or minerals were prescribed. Complementary risk management strategies instituted through labelling requirements were also developed.