**8 August 2001**
**02/02**

# INQUIRY REPORT

## APPLICATION A394

## FORMULATED CAFFEINATED BEVERAGES

**CONTENTS**

# 1. EXECUTIVE SUMMARY

## *1.1 Consultation*

The Full Assessment report for A394 was advertised at the end of November 2000 and 37 submissions from industry, consumers and public health professionals, government organisations were received in response. In addition, there has been targeted consultation with key stakeholders.

## *1.2 Assessment of issues raised at Inquiry and proposed outcomes*

### 1.2.1 Regulation

The proposal to develop a standard for formulated caffeinated beverages (FCBs) was predominantly supported at Full Assessment even by some who did not support the products *per se*, but were in favour of having better regulation for these products. If the proposed standard for FCBs is not endorsed by the Ministerial Council, the Trans Tasman Mutual Recognition Arrangement (TTMRA) will continue to operate to allow New Zealand and other international product to be imported into Australia, while at the same time domestic production of similar product would be prohibited. The grounds for limiting the operation of TTMRA are quite narrow and any exemptions require annual review.

Further consideration of draft Standard R11 within Volume 1 has not proceeded because that Volume is time limited. The draft Standard in Volume 2 of the Food Standards Code has been re-located from Standard 2.11.1 to Standard 2.6.4 within the non-alcoholic beverages section so as to treat FCBs as other forms of non-alcoholic beverages and not to accord them special status.

Support for the terms and definitions used in the draft Standard was divided and a number of alternative suggestions were made. The purpose clause and definition have been modified to focus on caffeine as the only essential ingredient, and to confine the purpose to enhancing mental performance. This revision also distinguishes these products from sports and electrolyte beverages whose purpose is related to physical performance. The revised definition for FCBs now reads: *Non-alcoholic water-based flavoured beverage which contains caffeine and may contain carbohydrates, amino acids, vitamins and other substances (including other foods) for the purpose of enhancing mental performance.* Comments on the definition and terminology for 'functional foods/products' have been deferred to the recently commenced review of dietary supplements (Proposal P235) and thus, will not be considered further within the context of A394.

### 1.2.2 Composition

Caffeine was raised by a number of submitters in relation to a range of potential detrimental health effects and the proposed maximum and minimum levels for caffeine in FCBs. Except for those opposed to caffeinated beverages *per se*, the maximum limit (320 mg caffeine/L of FCB) was widely accepted. There was however, considerable comment on the proposed minimum concentration of caffeine (145 mg caffeine/L of FCB) including concerns from manufacturers regarding the limited flexibility of formulations. The range of concentrations proposed at Full Assessment however, have been retained.

In November 2000, ANZFSC agreed to seek direction on the matter of caffeine addition to foods from the Ministerial Council on Drug Strategy (MCDS), particularly on caffeine use in conjunction with alcohol and /or other substances of dependence. The MCDS is currently considering its response out-of-session.

Because the submissions clearly highlighted community concern in relation to potential access to caffeinated beverages by children, and in response to the potential carry-over fortification from FCBs to other products, FCBs are proposed to be prohibited from being used as ingredients in other beverages commonly consumed by children, such as soft drinks.

Of all substances sought to be permitted in FCBs, only niacin and thiamin were considered due to the lack of supporting data for the other substances. Permissions for the addition of non-nutritive sweeteners have also been clarified now that FCBs are classified within section 2.6 of Volume 2.

1.2.3 Labelling

The proposed advisory statements were well supported by all submitters who commented and made suggestions for enhancing the intent. As a result of these comments, pregnant and lactating women are included in the '*not recommended for…*' statement and an alternative means of expressing the advised daily consumption limit is provided. The draft Standard has also been amended to ensure caffeine from all sources is captured in the relevant advisory statements. Also to advise consumers that health authorities recommend limiting caffeine intake generally.

Due to considerable debate around the prohibition on nutrition information, mandatory nutrition information is now required on FCBs, consistent with requirements for soft drinks. However the prohibition on vitamin claims and expressions as percentiles of dietary reference values has been maintained.

The requirement for a prescribed name received divided support. The general requirement in Standard 1.2.2(1) is now considered sufficient to address the naming requirements for FCBs and therefore the specific clause requiring a prescribed name has been deleted.

1.2.4 Other issues

A number of comments were largely based on concerns regarding availability and appeal to children; many queried the applicant's contention that the product is not marketed to children. Several ways of risk-managing potential exposure of formulated caffeinated beverages to children are under consideration. As there are limits to the measures that can be implemented through food standards, the matter is referred to the jurisdictions and other inter-governmental bodies such as the Strategic Inter-governmental Nutrition Alliance (SIGNAL) for consideration.

### *1.3 Regulation Impact Statement*

An amended Regulation Impact Statement has been provided (see Attachment 4) which has as its preferred option, full regulation supported by ANZFA's referral of the matter of FCB availability to children to the jurisdictions and health partnerships such as SIGNAL for consideration.

## 2. PREVIOUS AUTHORITY CONSIDERATION

### *2.1 Background*

The Full Assessment for A394 was made in November 2000 and the subsequent report advertised on 29 November 2000 for a twelve-week period of public consultation concluding 23 February 2001. The executive summary from the Full Assessment report is provided below:

### *2.2 Executive summary from the Full Assessment Report*

#### 2.2.1 Background

The Australia New Zealand Food Authority (ANZFA) received an application to amend the Australian *Food Standards Code* to include regulatory provisions for 'energy drinks'. In particular the applicant seeks permission for caffeine, B complex vitamins and other substances such as taurine, glucuronolactone and inositol to be added to 'energy drinks'.

#### 2.2.2 Consultation

A total of 13 submissions were received at preliminary assessment (refer to Attachment 7 of the Full Assessment report for A394). The majority of submitters (mostly representative of industry) supported development of a standard for regulation of 'energy drinks'. The three exceptions sought more information e.g. in relation to caffeine consumption and/or recommended a more extensive review of the current permissions for nutritive substances and guarana.

An expert external working party met in May 2000 to comment on particular components of the composition and labelling of 'energy drinks'. Comments from this working group were taken into consideration in finalising the Full Assessment report. Their considerations included:

- 'energy drinks' are the first part of a broader group of functional-type products that need to be considered as part of the broader review of dietary supplements
- caffeine, energy mediating substances (such as some of the B vitamins) and carbohydrates (as an energy source) are all important defining characteristics of 'energy drinks'
- justification for use of specific nutrients or substances should be provided in terms of their role in meeting any specific purpose, but not levels required to meet the purpose
- advisory statements should be used on 'energy drinks' to indicate that they are not appropriate for children, pregnant women or caffeine sensitive people
- some notification to the public is required that the product contains caffeine; comparative information about caffeine would be valuable; and
- quantitative compositional information should be provided.

#### 2.2.3 Issue

Currently, there is no standard in the Australian *Food Standards Code* or New Zealand *Food Regulations 1984* for 'energy drinks' such as *Red Bull energy drink* and 'energy drinks' contain levels of nutritive substances well in excess of levels currently permitted in the *Food Standards Code* both for general purpose foods and special purpose foods.

However, 'energy drinks' regulated in New Zealand under the *Dietary Supplement Regulations 1985* are permitted to be imported into Australia under the provisions of the

Trans-Tasman Mutual Recognition Arrangement (TTMRA) providing they comply with New Zealand regulations.

### 2.2.4 Policy

In the assessment of all applications, ANZFA has regard to Section 10 of the ANZFA Act 1991 and respective Australian and New Zealand trade competition policies. In addition, there are a number of policy principles that are being proposed which are specific to this application. These include that:

- 'energy drinks' are part of a newly defined category of foods (within the current and new joint *Food Standards Codes*) which differ from current representations of general purpose and special dietary purpose foods,
- combinations and levels of added substances should be based on evidence of safety rather than efficacy, except for defining added substances; and
- claims on 'energy drinks' should be subject to the same current prohibitions, or proposed conditions of substantiation, as health claims generally.

### 2.2.5 Definitions

There are currently no definitions for 'energy drinks' or the type of product they represent either in Australian or New Zealand food regulation, or within commonly accepted international use. The following working definitions have been proposed in conjunction with the assessment of this application.

**Formulated caffeinated beverages***: Non-alcoholic water-based beverages which contain caffeine and carbohydrate and may contain amino acid(s), vitamin(s) and other substance(s) (including other food(s)) for the purpose of providing real or perceived enhanced physiological and/or performance effects.*

Furthermore, it is proposed that the category of product, of which energy drinks are one example, be referred to as **Functional Products** and that this category be defined as: *Formulated products, similar in appearance to conventional foods, which have been modified beyond the provision of simple nutrient requirements for the purpose(s) of achieving real or perceived physiological and/or performance effects.*

### 2.2.6 Proposals

Regulation

It was proposed that formulated caffeinated beverages be regulated by the Australian *Food Standards Code* and the new joint *Australia New Zealand Food Standards Code* in discrete standards called **Formulated Caffeinated Beverages**.

These standards were drafted as Standard R11 in the current *Food Standards Code* and Part 2.11.1 in the joint *Australia New Zealand Food Standards Code.* In the latter case, it was considered this standard would be the first in a new part that may later be expanded to cater for a wider range of dietary supplement or functional-type food products.

Composition

The full assessment proposed that, with respect to composition, permissions for formulated caffeinated beverages be based on:

- all added substances and their amounts being subject to a safety assessment;

- specified amounts of characterising added substances be required (i.e. 145-320 mg/L of caffeine) in order to segregate the product from general purpose beverages;
- a conservative approach to permissions be adopted; and
- a list of positive permissions for added substances be provided.

As a result of the scientific risk assessment for this application, it was proposed that formulated caffeinated beverages be permitted to contain the following nutritive and biologically active substances as maximum amounts that may be added to a one-day quantity of product:

- Niacin 35 mg
- Riboflavin 20 mg
- Vitamin B6 10 mg
- Vitamin B12 10 mcg
- Pantothenic Acid 10 mg
- Taurine 2000 mg
- Glucuronolactone 1200 mg
- Inositol 100 mg

Caffeine from guarana and any other sources may be added to a maximum concentration of 320 mg/L, but should not be less than 145 mg/L.

Labelling

The following requirements were proposed:

- the labels on all formulated caffeinated beverages must declare quantities of energy, carbohydrate, caffeine from all sources and all added substances (added for non-technological purposes) per 100 mL and per serving in the form of a table;
- an advisory consumption limit be provided on the label;
- advisory statements be required to the effect that the product contains caffeine; and
- that the product is not recommended for children or caffeine sensitive people.

The following option was proposed:

- a statement or graphic used on the label to compare the caffeine concentration with a 'strong cup of instant coffee' where this could represent, for example, 80 mg of caffeine in a 250 mL cup;

The following exemptions/prohibitions were proposed:

- no health claims or enhanced function claims may be made on formulated caffeinated beverages unless specific approval has been granted [pending finalisation of proposal P153];
- formulated caffeinated beverages be prohibited from bearing a nutrition information panel;
- expression of nutritive substances as multiples or a proportion of recommended dietary intakes or equivalent, not be permitted; and
- vitamin [and mineral] content claims not be permitted [by virtue of Standards A9 and 1.3.2].

### 2.2.6 Consequential amendments

It was noted at Full Assessment that in order to accommodate this new type of product within current regulatory terminology, the definitions of nutritive substances in the current and new joint *Food Standards Codes* would need to be considered in relation to encompassing 'functional' as well as 'nutritional' roles. Amendments would also be required in respect of nutrition labelling requirements and additive permissions.

### 2.2.7 Further permissions

The Full Assessment considered in detail the substances added to *Red Bull energy drink.* ANZFA recognised that other formulated caffeinated beverages may contain different substances or different formulations.

ANZFA thereby invited submissions with sufficient detail to enable consideration of other extracted/refined substances that may contribute the development of a standard that is potentially more generic than the *Red Bull energy drink* formulation.

In respect of such submissions, submitters were referred to the Safety Assessment report for examples of the type of data required. The following additional information in relation to products containing these substances was also requested:

- nature of the product;
- history of use;
- market penetration;
- average consumption data; and
- compositional details including maximum concentrations of added substances.

### 2.2.8 Regulation impact Statement and World Trade Organization

It was considered at Full Assessment that the regulatory option beneficial to most stakeholders was the option of developing a food standard for formulated caffeinated beverages (as new standards in the Australian *Food Standards Code* and new joint *Australia New Zealand Food Standards Code).* This meant that formulated caffeinated beverages would be fully regulated and covered by a new category that includes particular compositional and labelling requirements.

As the preferred regulatory option involves the development of a new food standard and one for which there is no international regulation, a World Trade Organization (WTO) notification was made on the basis of constituting a Technical Barrier to Trade (TBT).

### 2.2.9 Conclusions

The report provided a full assessment on the Application A394 – Formulated Caffeinated Beverages (formerly Energy Drinks). These considerations proposed a way forward for this type of product and invited comment on various aspects.

*Regulation*

It was proposed that formulated caffeinated beverages be regulated in separate standards called *Formulated Caffeinated Beverages* in the current *Australian Food Standards Code* and the new joint *Australia New Zealand Food Standards Code.*

*Composition*

It was proposed that positive permissions for substances be given in these standards that would enable industry to manufacture non-alcoholic water-based beverages containing carbohydrates,

caffeine and other substances for which a safety/risk assessment has been conducted by ANZFA. All substances may be subject to maximum levels.

*Labelling*
It was proposed that this category of product would have specific labelling requirements relating to composition, consumption advice and characterisation of the product. Also, that there be certain permissions and prohibitions around the type of claims that may be made.

It was considered that the preferred regulatory option met the objectives of this application (A394) and in so doing addressed the issue of trade disparity between Australia and New Zealand.

ANZFA sought submissions on a number of aspects of the Full Assessment and in particular, wished to consider representations that may serve to broaden the scope of any new standards that arise as a result of this application.

## 3. SUMMARY OF NEW SUBMISSIONS RECEIVED AT INQUIRY

Thirty-seven submissions to the Full Assessment Report for A394, including 15 from industry, 16 from consumers and public health professionals and six from government organisations, were received and comments summarised. A full summary of submissions indicating the issues raised is provided at Attachment 3. Appended to Attachment 3, is a submission received more recently from the Australasian Soft Drink Association (ASDA) in response to targeted comments sought by ANZFA. Other key stakeholders with whom ANZFA has held further discussions include the applicant, the New Zealand Ministry of Health, the Australian Consumers' Association and the Senior Food Officers.

Given below is a summary of the overall support for the proposed draft standard, as gauged from submissions.

### *3.1 Support for proposal*

Overall, the proposed draft standard for formulated caffeinated beverages (FCBs) was supported subject to some qualifications. Even amongst those opposed to FCBs *per se*, it was acknowledged that if these products are to remain on the Australia market it was preferable that they be more effectively regulated. The view was also raised that they should not be available at all.

Indications of overall support for the proposal to develop a standard for FCBs were divided amongst the three stakeholder groups except for industry, who were largely in support of the basic principle to develop a standard for 'energy drinks' but with requests for greater flexibility in formulation.

The views were divided between the government representatives. Those three not in support were a local NSW council, the US Department of Agriculture and one State health department. These submitters expressed concerns relating to an [inappropriate] increased availability of the product to children; continued barriers to trade on the international market; and inconsistency with current conservative regulatory fortification policy thereby setting an inappropriate precedent.

Those in support of the proposal were the New Zealand Ministry of Health (MOH) and two State health departments. The MOH was amongst those supporting the proposal and noted in particular their support for developing a new category of 'functional foods', and with the qualification that consideration needs to be given to complementing and being consistent with existing standards.

Public health professionals and consumer representatives also presented mixed views. Those in support generally qualified their comments by adding that the support was because of a need to effectively regulate the products, rather than supporting them *per se*. Many expressed concern regarding the caffeine content and availability to children.

Industry submissions universally supported the intent of the proposal but there were many comments that the drafting was too prescriptive, mainly in relation to the restriction to caffeinated beverages and the limited list of positive permission for added substances.

# 4. ASSESSMENT OF ISSUES RAISED IN PUBLIC SUBMISSIONS AT INQUIRY

The following section discusses the issues raised at Full Assessment and highlights the intended changes to the draft Standard as a result of these considerations. Consequentially, the regulation impact statement (RIS) has been amended. This is discussed further in section 7 and the fully amended RIS is provided at Attachment 4.

### *4.1 Regulation*

The proposal to develop a standard for formulated caffeinated beverages has been supported at Full Assessment even by some who did not support the products *per se*, but were in favour of having their presence on the market better managed through regulation. Some submitters preferred that FCBs not be available at all. If the proposed standard for FCB is not endorsed by the Ministerial Council, the TTMRA will continue to operate to allow New Zealand and other international product to be imported into Australia, while at the same time product would be prohibited for domestic production. The grounds for limiting the operation of TTMRA are quite narrow and any exemptions require annual review.

**Assessment**

At Full Assessment, draft standards were presented for both Volume 1 and Volume 2 of the FSC. As Volume 1 is time limited, it is now proposed that the draft standard for FCBs in only Volume 2 be progressed, i.e. draft Standard 2.6.4, if adopted, will become the relevant standard.

The option for regulation of FCBs within the *Food Standards Code* has been further developed within the context of the Regulation Impact Statement (see Attachment 4) to also consider referring the matter to the jurisdictions for their consideration in terms of appropriate policies that could be used to restrict the availability of FCBs to children. Industry views were sought as to the level of interest in a code of practice, however, there was mixed support for this.

### *4.2 Terms and definitions*

*Formulated caffeinated beverages*

FCBs are defined in the Full Assessment report as*: Non-alcoholic water-based beverages which contain caffeine and carbohydrate and may contain amino acid(s), vitamin(s) and other substance(s) (including other food(s)) for the purpose of providing real or perceived enhanced physiological and/or performance effects.*

Support for this definition was divided. Some considered it an appropriate descriptor whereas, others noted that ANZFA's suggested definition may encourage therapeutic use or claims and furthermore, that this definition may set a precedent for similar fortification of other foods not generally considered conducive to good health and/or the addition of caffeine to other soft drinks.

A number of manufacturers considered that a standard restricted to caffeinated beverages (by virtue of the definition), or one which only addresses formulations containing >145mg/L caffeine, would stifle innovation and not ease current inequities in trade as a number of their formulations would still not be covered. It was noted that, as long as the TTMRA is still in place, overseas manufacturers would have an advantage over Australian industry. Furthermore, a number of products currently sold on the international market will not be able to be produced in Australia. It was suggested that the reference in the definition to containing caffeine be qualified by '*may contain caffeine'*.

It was suggested by the applicant that the word psychological be added to the above definition such that it reads: …… *for the purpose of providing real or perceived enhanced physiological, psychological and/or performance effects.*

A number of submitters considered that the word 'perceived' was unacceptable and had no place in the definition as it undermined the scientific rationale that supports the rest of the Food Standards Code. Instead, these submitters considered that formulations must be rational and substantiated. There was also recognition of potential enforcement issues. Furthermore, it was considered that since health claims were integral to this product category, it was untenable for the product definition to be incompatible with regulatory requirements. This would result in confusion and exacerbate non-compliance.

One submitter noted that the term 'stimulant' beverage (proposed as an alternative name for the standard at Full Assessment) was not supported because of possible links with drugs and the associated effects.

Comments in support of the term and definition noted that differentiation between these beverages, and sports and electrolyte drinks, was appropriate and that development of a specific standard for FCBs afforded a means of controlling composition, marketing and labelling of this particular type of product.

**Assessment**

ANZFA considers it appropriate to restrict this new standard to caffeinated beverages, and in order to clearly differentiate them from caffeinated soft drinks (these are permitted to have up to 145 mg/L caffeine) it is necessary to provide a minimum caffeine level.

A further definitional issue has also arisen in relation to the presence or otherwise of carbohydrate in FCBs. As discussed below in relation to the assessment of compositional issues (refer section 4.3), clarification on the additive permissions for FCBs has identified horizontal provision for addition of non-nutritive sweeteners to FCBs. Given this, and ANZFA's position that purpose of the product is not necessarily attained by the presence of carbohydrate, it is proposed that the definition be amended at Inquiry to allow for voluntary, rather than mandatory, presence of carbohydrate.

The word 'performance' in the definition was intended to address mental performance as the claims made by many functional products appear to relate to 'effects on the mind'. ANZFA accepts comments in relation to the above and proposes to reword the definition as follows. Formulated caffeinated beverages are:

*Non-alcoholic water-based flavoured beverage which contains caffeine and may contain carbohydrates, amino acids, vitamins and other substances (including other foods) for the purpose of enhancing mental performance.*

This amended definition also serves to maintain the distinction from sports and electrolyte beverages which are intended to enhance or optimise physical performance.

*Functional products/foods*

In order to provide a broader policy context, functional products/foods were discussed in the A394 Full Assessment Report and defined as: *Formulated products, similar in appearance to conventional foods, which have been modified beyond the provision of simple nutrient requirements for the purpose(s) of achieving real or perceived physiological and/or performance effects.* ANZFA recognises that clarification is required as to whether the category is referred to as 'functional products' or ' functional foods'.

In accordance with the discussion above on the definition for FCBs, the applicant suggested that the word psychological also be added to this definition such that it reads: *for the purpose of achieving real or perceived enhanced physiological, psychological and/or performance effects.*

Also similarly to above, there was again reference to the word 'perceived' - a number of submitters consider that this term is unacceptable and has no place in this context as it undermines the scientific rationale that supports the rest of the *Food Standards Code*. The term and development of this category of products was fully supported by industry. One group suggested that this category should also accommodate formulated supplementary and functional dairy products and that dietary supplements need to be clearly differentiated from formulated supplementary foods.

The MOH noted that functional foods/products need to be clearly distinguished from special purpose foods but suggested the term 'supplemented foods' may be more appropriate, as 'functional ' implies functions beyond normal and some of these foods may only contain extra nutrients. Other submitters also presented the view that the term 'functional foods' can be problematic as all foods are effectively functional. As a contrary view, it was proposed by another submitter that functional foods/products be addressed in a separate document as it considered that FCBs are not designed or intended to be functional foods/products.

**Assessment**

ANZFA has raised the issue of functional foods/products in order to provide a regulatory context that may relate to a draft standard for FCBs. As the review of dietary supplements (Proposal P235) has now commenced it is anticipated that further attention will be given to functional foods/products within the context of this review and that associated terminology and definitions should not be considered further within the context of A394.

Meanwhile, ANZFA maintains its position the FCBs should be regulated as a separate standard. This Standard has now been designated, at Inquiry, as Standard 2.6.4, rather than Standard 2.11.1 (as presented at Full Assessment) in accordance with the positioning of other non-alcoholic beverage standards.

### *4.3 Composition*

*Caffeine*

At Full Assessment the executive summary of the report of the Expert Working Group on Caffeine (EWGC) was attached, in respect of discussion on safety aspects of caffeine. In the final presentation of this EWGC report, a dissenting report was provide by Professor Jack James who found he was unable to agree with the final conclusions of the Group.
As noted by some submitters, this dissent was not referred to in the A394 Full Assessment report, and bears particular relevance to the discussions on the health outcomes associated with caffeine.

The author of this Inquiry Report acknowledges this omission and presents, at Attachment 5, the executive summary of the Expert Working Group report on Caffeine together with the executive summary of Professor James' dissenting report. The full report is available directly from ANZFA or via the ANZFA website (www.anzfa.gov.au).

Caffeine was raised by a number of submitters in relation to a range of potential detrimental health effects and the proposed maximum and minimum levels for caffeine in FCBs. The proposed maximum and minimum levels for caffeine were considered by a number of submitters. Except for those opposed to caffeinated beverages *per se*, the maximum limit (320 mg caffeine/L of FCB) was widely accepted. There was however, considerable comment on the proposed minimum concentration of caffeine (145 mg caffeine/L of FCB). Furthermore, it was considered by a number of manufacturers that a standard restricted to caffeinated beverages, or one which only addresses formulations containing >145 mg caffeine/L, will stifle innovation and will not ease current inequities in trade as a number of formulations on the market would still not be covered.

Consumption by children was by far one of the greatest concerns expressed by submitters in relation to this proposal. In his dissenting report, Professor James also notes that the harmful effects of caffeine 'probably extrapolate to children'.

**Further considerations**

In November 2000 it was agreed to seek direction on the matter of caffeine addition to foods from the Ministerial Council on Drug Strategy (MCDS). Senator Tambling has directed this matter to the MCDS, with particular emphasis on caffeine use in conjunction with alcohol and /or other substances of dependence. The MCDS is currently considering its response out-of-session.

The applicant offered to provide recent consumption data that indicates that regular consumers in a European cohort, aged 15-50 years-old, averaged 110 mL/day whilst high consumers averaged 250 mL/day however, no further details had been received at the time of writing this report. These indications are that regular consumption of FCBs is less than estimated at Full Assessment.

It was also anticipated that the University of Otago would provide some preliminary data from a pilot survey on 'energy drink' consumption by New Zealand children. These data were provided however, the information collected indicates that the beverages consumed are primarily the non-caffeinated variety (as permitted to be manufactured or imported in New Zealand) and therefore not of direct relevance to this report.

**Assessment**

These investigations have not brought to light any further information that would cause ANZFA to reconsider the caffeine permissions as they relate to composition of FCBs as proposed at Full Assessment therefore, no changes are proposed.

The Expert Working Group's conclusion given in the A394 Full Assessment Report was that, for adults, caffeine at doses typically consumed in the diet may lead to withdrawal effects and some physical dependence, but the prevalence of such effects has been variable, as the interpretation and their intensity is minimal in most individuals. For children, however, the Group concluded that the threshold dose for possible behavioural effects remains unclear and it is recognised that further studies are needed to elucidate the potential effects of caffeine in children at doses that may be ingested from dietary sources.

The submissions have clearly highlighted community concern in relation to potential access to caffeinated beverages by children therefore, ANZFA has given further consideration to the permission inherent within the FSC for mixing FCBs with other standardised foods that may result in carry-over caffeination to other products commonly consumed by children. Although the discussion at this point is focused on caffeine, ANZFA also has concerns in respect of carry-over fortification from FCBs to other products, which would not otherwise be permitted by the FSC.

Towards this end, ANZFA considers that FCBs should be excluded from the general arrangements allowing the mixture of standardised foods. In particular, FCBs should not be permitted to be mixed with beverages commonly consumed by children, specifically soft drinks (standardised in the *Food Standards Code* under 2.6.2).

*Expression of caffeine maximum limit*

It was identified that the means of limiting added substances was inconsistent such that caffeine was limited by volume (i.e. mg/L) whereas other substances were limited via daily consumption. Most submitters noted the current market presence of caffeine in various forms; their points related more to the desire to avoid a further proliferation of caffeinated products, particularly in forms which are seen to be appealing to children.

**Assessment**

The permissions for caffeine have been based on an anticipated amount per 250 mL can i.e. 80mg/can. If this permission were by daily limit (e.g. 160 mg/day), the amount in a 250 mL can could be doubled if just one can/day were the advised consumption, or halved if four cans /day were advised. It is considered this approach would be confusing and quite problematic, requiring diligent label-reading by consumers regarding anticipated caffeine consumption, and also start to 'blur' the lines between soft drinks and FCBs as the caffeine concentration decreased.

No changes are proposed to the means of quantitatively expressing caffeine in FCB labelling. Other aspects of access to caffeine from FCBs by children are discussed further below under packaging and marketing.

*Permissions for other added substances*

ANZFA specifically sought further information from submitters in relation to additional substances to be considered for inclusion in the permissions of the proposed standard. A number of substances were put forward by submitters, for either added or increased permission of vitamins A, $B_1$, $B_2$, $B_6$, $B_{12}$, C, E, calcium, iron, and non-nutritive sweeteners. In particular, submitters asked that non-caffeinated beverages also be considered.

A submission on behalf of the applicant provided a review on the health effects of niacin that suggests the daily consumption limit for niacin could safely be increased from the proposed 35 mg to at least 40 mg per one-day quantity of FCB.

Subsequent communications with these submitters resulted in withdrawal of the requests, except for thiamin, niacin and non-nutritive sweeteners, due to the difficulties of providing the supporting evidence required in the time available.

**Assessment- niacin**

Further consideration has been given to the safety assessment for niacin on the basis of further information from the applicant and also from ingredient suppliers to manufacturers of FCBs. The fundamentals of the safety assessment presented at Full Assessment still apply however, ANZFA considers that as susceptibility to niacin is subject to a number of idiosyncratic factors and the bioavailability of various forms of niacin also varies, there is scope for a moderate increase in the niacin permission for FCBs, whilst still adopting a relatively conservative approach. Furthermore, the form of niacin added to FCBs is generally nicotinamide rather than nicotinic acid with which the adverse effect of 'flushing' is generally associated. A revised version of the Safety Assessment Report is presented at Attachment 6.

The updated safety assessment of niacin concludes that consumers should be advised not to consume more than 40 mg niacin /day from formulated caffeinated beverages (which translates to no more than 2 cans of beverage containing 20 mg/250 mL serve, or 80 mg/L of FCB).

**Assessment - thiamin**

Thiamin is an essential coenzyme in the citric acid cycle, which has a pivotal role in the metabolism of fats, proteins and carbohydrates. The human body cannot store thiamin and thus there is rapid excretion of thiamin after large doses (5 mg/day). The maximum amount of oral thiamin absorption is estimated to be 5 – 10 mg /day (Institute of Medicine, 1998), after which the absorption declines and rapid excretion of thiamin occurs.

Consumption of thiamin as part of food or in supplements is not known to have a toxic effect even if consumed in large doses. In the US, no upper limits have been established for thiamin because there is no evidence of toxicity. Supplements of up to 50 mg/day are readily available without prescription.

Preliminary market surveillance indicates that the current levels of thiamin added to formulated caffeinated beverages range from 0.3 – 3.2 mg/100 mL.

As there is no evidence of toxicity from consumption of thiamin at high levels (up to 50 mg/day), a maximum limit of 20 mg/250 mL (80 mg/L) will accommodate known current market formulations of formulated caffeinated beverages whilst maintaining a relatively conservative approach to permissions. Within the context of advised daily consumption of *Red Bull* (calculated according to the permissions granted for other added substances) this would translate to 40 mg /one-day intake of thiamin from 2 x 250 mL cans of *Red Bull*.

Further information is provided in the revised Safety Assessment report at Attachment 6.

**Assessment – non-nutritive sweeteners**

Permissions already in Volume 2 of the Code in relation to non-nutritive sweeteners would apply to FCBs. This has been clarified through the amendment to the definition of FCBs as water-based flavoured drinks, which brings them within this category under Standard 1.3.1. (Item 14.1.3 in Schedule 1). This item in Standard 1.3.1 identifies a number of permitted additives to these beverages, including a range of non-nutritive sweeteners.

In accordance with this, the Purpose and Interpretation clauses of the draft standard have been amended such that addition of carbohydrate to these formulated caffeinated beverages is voluntary.

***4.4 Herbal substances***

Clarity was sought regarding the permissions or otherwise for herbs or herbal extracts, such as St John's Wort, Echinacea, Gingko and Ginseng, to be added to FCBs. It was considered that these should be permitted, particularly where a history of safe use exists. The intention at Full Assessment was that herbal substances could be added as they are included in the reference to …..*addition of other substances (including other foods).*…as identified under 'Interpretation' in Clause 1. Therefore, herbals can be added to FCBs subject to the provision of relevant standards in the Code such as Standard 1.3.1 – Food Additives and Standard 1.4.4

– Prohibited and Restricted Plants and Fungi. Herbal substances are not regarded as nutritive substances because they do not fulfil a nutritional purpose and as such are not required to specifically permitted in the *Food Standards Code*.

**Assessment**

ANZFA proposes to further clarify this issue at Inquiry by the insertion of an editorial note in the draft Standard 2.6.4.

***4.5 Labelling***

*Advisory statements*

The proposed advisory statements were well supported by all submitters who commented on this aspect although one submitter considered that compositional limits would be a more direct and preferable risk-management approach to usage by consumers. Some submitters also observed that advisory statements would not be a sufficiently effective risk management approach i.e. 'better protection' was needed, and that statements may even have the opposite effect of adding greater appeal to children.

Furthermore, there was interest in determining an appropriate age by which to define 'children' for the purposes of these beverages. Suggestions put to ANZFA from submissions and other discussions have proposed 12 years, 15 years, 18 years or 'school-age' children with the majority focusing on 15 years or 18 years. This issue is also specifically addressed in comments received recently from the industry (ASDA) where 12 is presented as an appropriate age. The relevant comments (received in response to targeted consultation by ANZFA) are contained within the ASDA letter, appended to Attachment 3.

Comments were also received in relation to the specific wording, prominence, type font, boldness and size of the advisory statements with the view that these statements need to 'stand-out'.

Reference to pregnant and lactating women was also raised with the suggestion that they be included in the statement advising against consumption. Comments made specifically in relation to caffeine consumption suggested that daily amounts should be advised, and differentiated for adults and children, and that caffeine from specific sources e.g. guarana, should be identified. The use of a pictogram, e.g. cup of coffee, to indicate caffeine content was not widely supported due to being insufficiently definitive and potentially confusing.

It was considered by some submitters that advised daily consumption limits did not sufficiently differentiate from the dosage approach and that the wording should be changed to clearly reflect that the amount should not be exceeded. Another suggestion was to advise consumption on the basis of 'cans per day' rather than millilitres.

**Assessment**

The advisory labelling statements proposed by ANZFA at Full Assessment have been widely supported and will be maintained, subject to some amendments, in the draft standard. Issues in relation to format, wording and presentation of the statements are governed by the relevant horizontal standards within Volume 2 of the Code, specifically Standards 1.2.9 and 1.1.1 (clause 12). Statements within any new standards for FCBs are subject to these horizontal permissions. In essence, the statements must be in English, legible and prominent, and words used that are 'to the effect of' (rather than actual wording being mandated).

Products not required to bear a label, such as mixed drinks served in a public bar, need to also be considered in relation to the advisory statements. This aspect will need to be addressed in the consequential amendments to ensure that advisory statements relating to FCBs are captured.

ANZFA agrees that a 'dosage' approach to advised consumption is inappropriate and the words proposed at Full Assessment i.e. "consume no more than…." were intended to avoid the dosage approach. No suggestions were received that appeared to more clearly identify the intent than those already proposed therefore, no amendment will be made to this section of the drafting. It is acknowledged however, that expression as 'cans' rather than 'millilitres' may be appropriate and the drafting will be clarified to allow for this flexibility.

ANZFA agrees that FCBs should not be recommended for pregnant or lactating women, and acknowledges reference to 'caffeine-sensitive' people may not adequately address this sub-group. ANZFA proposes to amend the draft standard to specifically include pregnant and lactating women in the respective advisory statement.

The assessment provided by the Expert Working Group on caffeine (as reported in the Full Assessment Report for A394) indicates the difficulties of identifying an observed-effect level for caffeine. Individuals vary considerably in relation to their sensitivity to caffeine, and particularly so for children in whom relative body weight and previous exposure to caffeine are also major factors. There is also the more extreme view that 'zero' is the only categorically safe level. It would therefore be very difficult to nominate an 'advised daily consumption' for caffeine that is either practical or meaningful for either children or adults.

Similarly, although a number of sound arguments were put forward for nominating an applicable age for children, ANZFA considers that to do so in legislation would be arbitrary and may have the unintended effect of encouraging use by younger children wanting to 'be seen to be older'. It is the view of ANZFA that interpretation of 'child' and suitability of consumption of FCBs is best determined by parents and carers, assisted by sufficient labelling to enable informed choice.

Nevertheless, there is considerable community concern about the exposure of consumers to caffeine given the increasing diversity of foods containing caffeine, often from the use of guarana as an ingredient. A press report in July 2001 of FCBs being implicated in 3 deaths in Sweden has heightened this concern. Perusal of several sources of advice from Australian and New Zealand government and health non-government organisations shows a diversity in approach to managing health-related advice concerning caffeine intake. Not all sources issue advice for the healthy adult population, but most issued advice for pregnant women. Some sources quantified their advice for adults in terms of mg of caffeine per day or numbers of

cups of coffee, but nearly all sources advised a maximum (lower) caffeine mg/day for pregnant women. Different amounts of caffeine are quoted among the sources, but mostly in the safe range between 200 and 600mg caffeine per day for adults, and 200-320mg/day for pregnant women.

To assist consumers consider their total caffeine intake, and to reinforce the general public health message to the community about limiting coffee or caffeine intake, it is proposed that an additional label advisory statement be required on labels of FCBs to the effect that 'health authorities recommend limiting caffeine intake'. It is important for this information to be given in connection with the products that are new or non-anticipated dietary sources of caffeine to complement current community knowledge about other well-known sources of caffeine such as coffee.

The draft Standard requires an advisory statement around consumption limits for FCBs however, this statement does not apply to those FCBs that do not contain any added substances (other than caffeine) due to the difficulties in nominating an appropriate daily caffeine limit. The draft Standard has been amended at Inquiry to clarify this provision.

Potential avenues for further risk-managing FCBs, in addition to labelling statements, have been considered by ANZFA and are discussed within the context of the amended Regulation Impact Statement (see Attachment 4). It is suggested that the jurisdictions consider appropriate measures to restrict the availability to children such as in schools or school sporting teams.

Due to the lack of support for the 'pictogram' as a means of comparing FCBs with cups of coffee, it is proposed that this approach not be explored further. As it was presented as a voluntary approach at Full Assessment, it was not included in the draft standard therefore, no drafting amendments are applicable.

*Compositional labelling*

The proposed drafting included requirements for detailed compositional labelling (as distinct from nutritional labelling), including declaration of energy and carbohydrate content. The comment was received that declaration of sugar content should also be required.

It was noted by some submitters that such formulated beverage labelling may give the misleading impression the products are vitamin supplements and, that permissions should be based on levels well below the acceptable intakes as consumers may not see the label information e.g. where energy drinks are purchased as mixed drinks in a public bar. Furthermore, products sold as mixed drinks over the counter do not bear labelling information.

No specific comments were received in relation to the proposed tabular format for the compositional information, it is therefore assumed that this approach is acceptable. However, the applicant raised the point that by requiring compositional declarations quantified per 100 g, this would have the effect of 'percentage labelling' many of the characterising ingredients and therefore, the percentage labelling required by virtue of the horizontal provisions of Standard 1.2.10 would be, in effect, superfluous.

**Assessment**

The issue of sugar declaration has been considered in the light of nutritional labelling information, as presented in the next section below.

ANZFA considers that the need for consumers to be aware of the composition of FCBs outweighs the disadvantages of perceptions as vitamin supplements due to compositional labelling. It would be highly desirable for consumers to be further educated as to the significance of the composition of FCBs and this may be further considered through means other than product labelling.

Where a label is not provided, e.g. over the counter sales of pre-opened product, the draft Standard needs to be amended to ensure that such FCBs subject to declaration requirements. For the avoidance of doubt, Standard 1.2.1 should also be amended to reflect this requirement for food not required to bear a label.

Similarly in relation to percentage labelling, this situation is not unique to FCBs and has previously been raised through the development of Standard 1.2.10. ANZFA considers it would be inappropriate for specific circumstances to apply to FCBs in relation to this matter and therefore, in the interests of maintaining consistency throughout the Code, the horizontal requirements for percentage labelling will apply equally to FCBs. Percentage labelling applies to the characterising ingredient or component, and is not expected to apply to all substances in the formulation.

*Nutritional labelling*

Considerable discussion arose about the proposed prohibition on nutritional labelling of FCBs, which would otherwise be required by the mandatory provisions of Standard 1.2.8 (Nutrition Information Requirements).

Views on the merits or otherwise of including nutritional labelling *per se* on these products were divided. Consumers, public health professionals and the New Zealand Ministry of Health supported the proposal to prohibit nutritional labelling on the basis that it sends misleading messages to consumers in relation to the role of the product in normal dietary intake, particularly as these products contain substantial amounts of added nutritive substances thereby indicating that they have a health-promotional role. It was considered that this potential misperception is exacerbated by the unproven nature of the physiological role these products may play.

Similarly, consumers and public health professionals agreed that nutrition claims and claims relating to added nutritive substances expressed as a percentage of nationally recommended or estimated dietary intakes (e.g. %RDI, %RDA or % ESADDI) were inappropriate again, on the basis of sending potentially misleading messages and indications that these beverages could be construed as vitamin supplements or otherwise nutritionally beneficial.

Contrary views were provided by some submitters including the US Department of Agriculture. The US Department of Agriculture noted that the absence of nutrition information would be incompatible with US requirements and furthermore, that complete nutrition information is necessary and not an endorsement of ‘healthy’. [It should also be noted that the formats for nutritional information differ between Australia New Zealand and the US and therefore would still be incompatible even if required]. It was further suggested

by another submitter that the provision of such information would be appropriate for demonstrating the lack of inherent nutritional value in these products.

Representations from a number of non-alcoholic beverage manufacturers and their representative organisation questioned the reasoning for prohibiting a nutrition information panel. They noted the inconsistency of this approach with the recent introduction of mandatory provisions for nutrition information for other non-alcoholic beverages. It was also noted that there was 'no point' in adding nutritive substances if their presence could not be claimed.

**Assessment**

ANZFA notes both sides to this argument and has considered this issue further.

*Nutrition Information Panel*
On balance, ANZFA considers that consistency in relation to application of horizontal provisions throughout the Code is a priority, and thus reverses its recommendation at Full Assessment to prohibit nutrition labelling as provided by the mandatory nutrition information panel (refer Standard 1.2.8).

The inclusion of nutritional labelling, in conjunction with compositional labelling, on FCBs raises the issue of label space and formatting requirements. In the interests of conserving space it would seem appropriate to combine the nutritional and compositional information into one table, as far as possible, whilst maintaining the formatting requirements of Standard 1.2.8 (Nutrition Information Requirements). An example is provided below.

| **NUTRITION INFORMATION** | | |
|---|---|---|
| Servings per package: (insert number of servings) | | |
| Serving size: 250mL | | |
| | Quantity per Serving | Quantity per 100 mL |
| Energy | kJ (Cal) | kJ (Cal) |
| Protein | g | g |
| Fat, total | g | g |
| -saturated | g | g |
| Carbohydrate, total | g | g |
| -sugars | g | g |
| Sodium | mg (mmol) | mg (mmol) |
| **COMPOSITION INFORMATION** | | |
| Caffeine | mg | mg |
| Thiamin | mg | mg |
| Niacin | mg | mg |
| Vitamin $B_6$ | mg | mg |
| Vitamin $B_{12}$ | µg | µg |
| Pantothenic acid | mg | mg |
| Taurine | mg | mg |

| | | |
|---|---|---|
| Glucuronolactone | mg | mg |
| Inositol | mg | mg |

This approach is provided as an example in the draft Standard, but ensures flexibility subject to maintenance of the horizontal requirements of Standard 1.2.8. That is, composition information can be adjacent to nutrition information - it does not necessarily need to follow it, as in the example.

*Nutrition claims*

ANZFA maintains its position that nutrition claims (specifically those relating to vitamins), and claims relating to added nutritive substances expressed as a percentage of nationally recommended or estimated dietary intakes (e.g. %RDI, %RDA or % ESADDI), are inappropriate. Whilst most aspects of misleading representation can be dealt with through fair trading laws, this type of product and its purpose are not clearly understood by many consumers. ANZFA considers regulatory support is warranted in relation to vitamin claims about the product that may not be addressed by fair trading laws.

ANZFA notes that, although the intention to prohibit nutrition claims was clearly discussed in the Full Assessment Report, specific drafting in relation to this matter was not included in the proposed standard nor a specific reference made to vitamin claims. It is therefore proposed that the drafting be amended at Inquiry to clearly address this aspect by specifically declaring that FCBs are not claimable foods for the purposes of vitamin claims. This means that vitamins can only be mentioned in a label in the compositional panel and the ingredient list.

It should be noted that the required compositional declarations of nutritive substances in the label do not constitute claims, by virtue of the fact that they are mandatory information (refer to Standard 1.1.1, clause 2).

### *4.6 Prescribed name*

*Prescribed name*

The applicant noted that if the name ‘Formulated Caffeinated Beverages’ were to be prescribed on the product label this would constitute a barrier to trade, as it has no international relevance or precedent. Furthermore, this name was considered to be unsuitable because it was unwieldy, too long and unfamiliar to consumers. On the other hand, some jurisdictions in particular, South Australia, were keen that it be retained to assist with enforcement processes.

**Assessment**

ANZFA has considered this aspect further, specifically within the context of relevant provisions within clause 1 of Standard 1.2.2, which states that where the name of a food is not prescribed, a name or description of the food sufficient to indicate the true nature of the food must be included in the label on the package. ANZFA considers that this requirement is sufficient to address the naming requirements for FCBs and therefore, it is proposed that the clause requiring a prescribed name in the proposed draft Standard be deleted.

### *4.7 Other issues*

*Marketing and packaging*

There were a number of comments on the way in which FCBs are currently marketed and packaged and suggestions given for future risk-management approaches. The comments were largely based on concerns regarding availability and appeal to children and that the applicant's contention that the product is not marketed to children does not appear to be borne out in practice.

It was noted that despite (or even because of) the advisory statements regarding non-suitability for children, marketing of and ready access to these products encourages consumption by some children and adolescents. Furthermore, the products are often accompanied by appealing advertising with no mention of caffeine.

Although there were some suggestions to manage the risk to children by limiting container size, it was also noted that this approach may be problematic due to potential restrictions on trade and competition policy guidelines.

Suggestions received included:

- any attempts to resemble soft drinks should be avoided;
- avoid the creation of a 'back door' avenues for manufacture of highly supplemented drinks that are mixtures of energy drinks and other beverages;
- monitor distribution through vending machines with sites not being close to schools; and
- avoid 'slogans' appealing to stressed or depressed young people such as 'vitalise body and mind' or suggested enhancement of performance effects.

It was also noted that the current and recent media attention on 'energy drinks' has inadvertently aided their promotion to young people.

**Assessment**

ANZFA proposes to consider ways of managing potential exposure of formulated caffeinated beverages to children. As there are limits to the measures that can be implemented through bi-national legislation, ANZFA refers the matter to the jurisdictions and health partnerships such as SIGNAL (cross-government nutrition alliance) to advise the community further, and work with educational institutions and the industry in addressing this issue. The major industry players have indicated that, while they are not in favour of a code of practice, they would be prepared to restrict availability of their product to children at school. Advice from the applicant, *Red Bull* on the matter of a code of practice, is given at Appendix 1 to Attachment 4. The Australasian Soft Drink Association's policy on school canteens reads:

*"The Australasian Soft Drink Association whilst recognising that there are no issues of health and safety associated with the normal consumption of 'formulated caffeinated beverages' (energy drinks) by children, nevertheless recognises that these products are formulated and marketed as adult non-alcoholic refreshments and therefore recommends to all members that Formulated Caffeinated Beverages (Energy Drinks) be labelled as not "recommended for children". In view of the above, we therefore suggest that School*

*Canteens should consider the suitability of 'energy drinks' for sale to children within school premises."*

# 5. CHANGES TO FULL ASSESSMENT/RIS RESULTING FROM INQUIRY

The following changes to the draft Standard 2.11.1 are proposed at Inquiry.

### *5.1 Placement of the Standard in the Food Standards Code*

Draft Standard 2.11.1 has been re-positioned as draft Standard 2.6.4 in accordance with the positioning of other non-alcoholic beverages in Volume 2 of the *Food Standards Code*.

### *5.2 Purpose of the standard*

The purpose clause has been amended to more clearly reflect the purpose of FCBs. The purpose clause is now worded: *The purpose of this Standard is to regulate non-alcoholic water-based flavoured formulated caffeinated beverages that are manufactured for the purpose of enhancing mental performance.*

### *5.3 Terms and definitions*

The definition of FCBs (refer Clause 1) has been amended to more appropriately reflect the compositional permissions for FCBs and to be consistent with the amended purpose clause. Amended definition*: **formulated caffeinated beverage** means a non-alcoholic water-based flavoured beverage which contains caffeine and may contain carbohydrate, amino acids, vitamins and other substances, including other foods, for the purpose of enhancing mental performance.*

The definition of one-day quantity (refer clause 1) has been amended to make it clear that this is the upper limit that should be consumed in one day.

### *5.4 Composition*

An editorial note has been added to subclause 2(1) to clarify the interaction with Standard 1.3.1 (Food Additives).

Amendments have been made to Table to subclause 2(2) to slightly increase the one-day maximum permission for niacin to 40mg and to include thiamin in the permitted list with a one-day maximum of 40mg.

An editorial note has been added following subclause 2(3) in order to clarify the permissions for addition of herbal substances.

Clarification of FCBs as water-based flavoured drinks has more clearly identified the relevant additive permissions within Standard 1.3.1.

### *5.5 New compositional clause*

New subclause 2(3) has been added to prohibit the mixing of FCBs with non-alcoholic beverages that are standardised under Standard 2.6.2.

### *5.6 Advisory statements*

Subclause 3(3) has been amended to require the inclusion of 'pregnant or lactating women' in relation to the advisory statement recommending against consumption by vulnerable groups. It also contains a new paragraph that requires a statement to the effect that health authorities recommend limiting caffeine intake.

Subclause 3(4) has been amended to allow greater flexibility in relation to the expression of the advised consumption limit and to clarify that the requirement is triggered only on the basis of the substances listed in the Table to subclause 2(2).

A new subclause has been added to address the requirements for products not required to bear a label.

An editorial note has been inserted after subclause 3(4) to explain the way in which the advised consumption limit should be determined.

### *5.7 Nutritional labelling*

The prohibition on nutrition information requirements has been deleted whilst the intended prohibition on vitamin claims and vitamins expressed as a percentage of nationally recommended or estimated dietary intakes (e.g. %RDI, %RDA or % ESADDI) has been clarified by the addition of subclause 3(6) and consequential amendment to Standard 1.3.2.

Subclause 3(2) has been amended to cater for the addition of a nutrition information panel and an editorial note that shows an example of combined presentation of nutrition and composition information. It has been proposed that compositional information may be included adjacent to or following the nutrition information panel.

### *5.8 Prescribed name*

Subclause 3(5) requiring the use of 'formulated caffeinated beverages' as a prescribed name has been deleted.

## 6. CONSEQUENTIAL AMENDMENTS

A consequential amendment has been added to the Purpose statement in Standard 1.3.2 to make it clear that the provisions of that standard do not apply to FCBs since draft Standard 2.6.4 specifically declares such beverages not to be claimable foods for the purposes of making vitamin and mineral claims.

A consequential amendment has also been made to Standard 1.2.1 (subclause 2(2)) to ensure the advisory statements pertaining to FCBs are also captured in relation to products not required to bear a label.

It was noted at Full Assessment that in order to accommodate this new type of product within current regulatory terminology, consequential amendment would be required to the definition of nutritive substances (refer Standard 1.1.1) in order to encompass 'functional' as well as 'nutritional' roles. This change in definition has not been considered necessary at Inquiry.

It was also anticipated that amendments would also be required in respect of nutrition labelling requirements and additive permissions. These consequential amendments are not required as it is considered that the provisions within the draft Standard 2.6.4 adequately address these matters.

## 7. REGULATION IMPACT STATEMENT (RIS)

The Office of Regulatory Review (ORR) has provided comment on the RIS as presented at Full Assessment. These comments, in conjunction with the changes to Standard 2.6.4 [formerly 2.11.1] now proposed at Inquiry, have been taken into account and an amended RIS prepared. The fully amended RIS is presented at Attachment 4.

The main change reflected in the amended RIS is the further development of full regulation, to full regulation supported by reference of the matter to the jurisdictions to potentially restrict product availability to children. An industry code of practice was raised with the industry organisation and major players, but there was mixed support. The response from *Red Bull* is given at Appendix 1 to Attachment 4.

## 8. CONCLUSIONS

In respect of the changes made to the assessment of this matter since Full Assessment, it is recommended that draft Standard 2.11.1 be re-positioned as draft Standard 2.6.4.

Furthermore, it is recommended that:

- the purpose clause and interpretation of formulated caffeinated beverages be amended;
- the compositional permissions for added substances be expanded and clarified;
- the mixing of FCBs with non-alcoholic beverages and brewed soft drinks standardised under Standard 2.6.2 be prohibited;
- some of the advisory statements be amended, made more flexible and/or clarified;
- a new advisory statement be included to the effect that health authorities recommend limiting caffeine intake;
- the prohibition on the use of a nutrition information panel be deleted;
- the prohibition against vitamin claims be clarified;
- the prescribed name requirement be deleted; and
- consequential amendments be made to Standards 1.3.2 and 1.2.1.

Further management of caffeine intake will be referred to the jurisdictions.

## ATTACHMENTS

1. Proposed Variations
2. Statement of Reasons
3. Summary of submissions received at Inquiry
4. Amended Regulation Impact Statement
5. Executive summary of the Expert Working Group report on caffeine and the executive summary of Professor James's dissenting report.
6. Safety Assessment Report

**ATTACHMENT 1**

***VARIATION TO THE FOOD STANDARDS CODE***

To commence: On gazettal

*The Food Standards Code is varied by -*

[1] *inserting immediately following Standard 2.6.3 -*

# *Standard 2.6.4*

# *Formulated Caffeinated Beverages*

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**Purpose**

The purpose of this Standard is to regulate non-alcoholic water-based flavoured formulated caffeinated beverages that are manufactured for the purpose of enhancing mental performance.

**Table of Provisions**



## 1 Interpretation

In this Standard –

**caffeine** means all caffeine present from whatever source in a formulated caffeinated beverage.

**formulated caffeinated beverage** means a non-alcoholic water-based flavoured beverage which contains caffeine and may contain carbohydrates, amino acids, vitamins and other substances, including other foods, for the purpose of enhancing mental performance.

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

## 2 Composition

(1) A formulated caffeinated beverage must contain no less than 145 mg/L and no more than 320 mg/L of caffeine.

**Editorial note:**

Standard 1.3.1 (Item 14.1.3 of Schedule 1) regulates food additives for the purposes of this standard.

The addition of caffeine to formulated caffeinated beverages goes beyond a technological function under Standard 1.3.1 and, therefore, the permission for the addition of caffeine is located in this Standard rather than in Standard 1.3.1.

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

Table to subclause 2(2)

| **Column 1** | **Column 2** |
|---|---|
| **Substance** | **Maximum amount per one-day quantity** |
| Thiamin | 40 mg |
| Riboflavin | 20 mg |
| Niacin | 40 mg |
| Vitamin $B_6$ | 10 mg |
| Vitamin $B_{12}$ | 10 µg |
| Pantothenic acid | 10 mg |
| Taurine | 2000 mg |
| Glucuronolactone | 1200 mg |
| Inositol | 100 mg |

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

**Editorial note:**

Other foods such as herbal substances may be added to formulated caffeinated beverages unless this is proscribed elsewhere in the Food Standards Code.

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

## 3 Labelling

(1) The label on a package of formulated caffeinated beverage must include declarations of the average quantities, per serving size and per 100 mL of –

(a) caffeine, expressed in milligrams; and
(b) the substances listed in column 1 of the Table to subclause 2(2) expressed in the units included in column 2 of the Table.

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

**Editorial note:**

An example of the placement of the declarations required under subclause 3(1) adjacent to or following a nutrition information panel as permitted under subclause 3(2) is set out below.

| **NUTRITION INFORMATION** | | |
|---|---|---|
| Servings per package: (insert number of servings) | | |
| Serving size: 250mL | | |
| | Quantity per Serving | Quantity per 100 mL |
| Energy | kJ (Cal) | kJ (Cal) |
| Protein | g | g |
| Fat, total | g | g |
| -saturated | g | g |
| Carbohydrate, total | g | g |
| -sugars | g | g |
| Sodium | mg (mmol) | mg (mmol) |
| **COMPOSITION INFORMATION** | | |
| Caffeine | mg | mg |
| Thiamin | mg | mg |
| Riboflavin | mg | mg |
| Niacin | mg | mg |
| Vitamin $B_6$ | mg | mg |
| Vitamin $B_{12}$ | µg | µg |
| Pantothenic acid | mg | mg |
| Taurine | mg | mg |
| Glucuronolactone | mg | mg |
| Inositol | mg | mg |

(3) The label on a package of formulated caffeinated beverage must include advisory statements to the effect that –

(a) the food contains caffeine; and
(b) health authorities recommend limiting caffeine intake; and
(c) the food is not recommended for –

(i) children; and
(ii) pregnant or lactating women; and
(iii) individuals sensitive to caffeine.

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

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

(5) Where a formulated caffeinated beverage is not required to bear a label pursuant to clause 2 of Standard 1.2.1, the advisory statements under subclauses 3(3) and 3(4) must be -

(a) displayed on or in connection with the display of the food; or
(b) provided to the purchaser on request.

**Editorial note:**

The advised one-day quantity is calculated from the permissions in the Table to subclause 2(2) as it relates to the concentration of substances in the product. The substance that yields the lowest equivalent amount will determine the advised consumption limit.

For example:

| Column 1 | Column 2 | Column 3 | Column 4 |
|---|---|---|---|
| Product X formulation | Concentration (mg/L) | Maximum permitted one-day quantity (refer to Table to subclause 2(2)) | Equivalent amount of product X (mL) |
| Riboflavin | 30 | 20 | 666 |
| Niacin | 80 | 40 | 500 |
| Pantothenic acid | 15 | 10 | 666 |
| Taurine | 2000 | 2000 | 1000 |

The equivalent amount in Column 4 is calculated as $\frac{\text{Column 3 x 1000}}{\text{Column 2}}$

In this example niacin presents as the most limiting substance, and therefore, the advised consumption limit for product X would be 500mL. If product X is packaged in 250mL cans, the advised consumption limit may also be expressed as 'two cans' – for example –

"consume no more than 500mL per day" or "consume no more than two cans per day".

(6) A formulated caffeinated beverage is not a 'claimable food' in Standard 1.3.2.

(7) The label on a package of formulated caffeinated beverage must not include declarations of the quantities of vitamins present in the food expressed as a proportion or multiple of the -

(a) Recommended Dietary Intakes; or
(b) Estimated Safe and Adequate Daily Dietary Intakes;

of that vitamin.

[2] *omitting paragraph 2(2)(l) of Standard 1.2.1, and substituting –*

(l) subclause 3(2) of Standard 2.6.3; and
(m) subclause 3(3) of Standard 2.6.4; and
(n) subclause 3(4) of Standard 2.6.4.

[3] *inserting into the 'Purpose' in Standard 1.3.2, immediately after the words* Standard 2.4.2 –

, the addition of vitamins to formulated caffeinated beverages in Standard 2.6.4

**ATTACHMENT 2**

**STATEMENT OF REASONS**

**APPLICATION A394**

**FOR RECOMMENDING ADOPTION OF DRAFT STANDARD 2.6.4 - FORMULATED CAFFEINATED BEVERAGES IN VOLUME 2 OF THE *FOOD STANDARDS CODE*, TO REGULATE THE COMPOSITION AND LABELLING OF FORMULATED CAFFEINATED BEVERAGES**

The Australia New Zealand Food Authority has before it an application received on 13 May 1999 from Red Bull GmbH to amend the Australian *Food Standards Code* (Volume 1*)* to include appropriate regulatory provisions for 'energy drinks' – *viz* non-alcoholic water-based carbonated beverages containing caffeine, B complex vitamins and other substances, now referred to as formulated caffeinated beverages (FCBs). As Volume 1 is time-limited and the application sought new permissions, the recommendation refers only to the Australia New Zealand *Food Standards Code* (Volume 2).

The Australia New Zealand Food Authority recommends the adoption of the draft Standard 2.6.4 (presented at Full Assessment as draft Standard 2.11.1), as amended, for the following reasons:

1. The proposed Standard protects public health and safety by controlling the maximum level of caffeine and other substances used in product formulation, and by requiring several label statements that advise maximum consumption, but also to advise against consumption by children, pregnant and lactating women and caffeine sensitive people. A general advisory statement is also required that health authorities recommend limiting caffeine intake.
2. The proposed standard requires detailed compositional information to be given on the label to enable informed choice by consumers.
3. An Australia New Zealand food standard reduces the current manufacturing and trade inequities between the two countries resulting from operation of the New Zealand *Dietary Supplements Regulations* 1985 (under which FCBs are permitted in New Zealand), and operation of the Trans Tasman Mutual Recognition Arrangement that permits unilateral trade in these beverages into Australia. Complete equity will be achieved when FCBs are no longer regulated in accordance with the New Zealand *Dietary Supplement Regulations*.
4. ANZFA refers the issue of restriction of availability of FCBs to children to the jurisdictions for consideration .

The drafting prepared after Full Assessment is amended as indicated below and for the following reasons:

- The **purpose clause and interpretation** of FCBs have been amended to more clearly reflect the purpose of the product, ie to enhance mental performance, and to more clearly identify the applicable additive permissions, ie those pertaining to water-based flavoured drinks. An interpretation of 'caffeine' has been added to clarify applicability of the term to <u>all</u> sources of caffeine, including from guarana.

- The **compositional provisions** have been amended to clarify additive and mixed-food permissions, to broaden the scope of the standard and to facilitate risk-

management of exposure from FCBs to non-target consumers. The latter point relates to the addition of a new sub-clause that prohibits the mixing of FCBs by food manufacturers with non-alcoholic beverages and brewed soft drinks standardised under Standard 2.6.2. The scope of the standard has been broadened by a new permission to add thiamin and an increase in the maximum permitted level of niacin. Applicability of the additive permissions for water-based flavoured drinks also means that non-nutritive sweeteners may be used in FCBs.

- The **labelling provisions** have been amended to clarify and facilitate the labelling requirements. In particular: the prohibition on the provision of a nutrition information panel has been removed and requirements included as to appropriate formatting of nutritional and compositional information; the advisory statement regarding *not recommended for consumption by…* has been amended to include pregnant and lactating women; the means of expressing advised consumption limits have been amended to allow for alternative forms of expression; guidance has been provided for calculating the advised consumption limits; and a new clause has been inserted to prohibit vitamin claims being made for these products. A new requirement has been added for the label to bear general advice that health authorities recommend limiting caffeine intake.

- The clause requiring a **prescribed name** in the label has been deleted as it was considered that the naming aspects were adequately addressed by other provisions within Volume 2 of the FSC.

- **Consequential amendments** have been added to: the Purpose of Standard 1.3.2 to make it clear that the provisions of that standard do not apply to FCBs since draft Standard 2.6.4 specifically declares such beverages not to be claimable foods for the purposes of making vitamin and mineral claims; and Standard 1.2.1 in order to address advisory statements on formulated caffeinated beverages not required to bear a label.

It is recommended that the commencement date of the proposed Standard be the date of gazettal. This would permit Australian manufacturers to enter the market without delay. As it is expected that the New Zealand *Dietary Supplement Regulations* will continue to provide permission for FCBs produced or imported into New Zealand, until probably next year, there should be adequate time for those manufacturers to make necessary label and/or compositional adjustments.

## REGULATION IMPACT

The Authority has undertaken a regulation impact assessment process which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the amendment to the *Food Standards Code* is necessary, cost effective and of benefit to both producers and consumers. It will however, considerably increase competition for New Zealand and third country manufacturers in the Australian market and, to a lesser extent, the New Zealand market.

## WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

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 Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances, Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

This matter was notified to the WTO as a technical barrier to trade (TBT) because no Codex standard or other international precedents for FCBs exist.

## FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code,* as gazetted in New Zealand, or the New Zealand *Food Regulations 1984,* but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *(Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999.*

- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code,* but not a combination of the two.

- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the New Zealand *Food Regulations 1984.*

- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts.*

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the Australian *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

**FURTHER INFORMATION**

**Submissions**: No submissions on this matter are sought as the Authority has completed its assessment and the matter is now with the Australia New Zealand Food Standards Council for consideration.

**Further information** on this and other matters should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the following addresses:

PO Box 7186
Canberra Mail Centre ACT 2610
AUSTRALIA
Tel (02) 6271 2258
email: slo@anzfa.gov.au

PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 4739942
email: anzfa.nz@anzfa.gov.au

Requests for copies of the full Inquiry Report or other information papers should be addressed to the Authority's Information Officer at the above address, or Email info@anzfa.gov.au

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***VARIATION TO THE FOOD STANDARDS CODE***

To commence: On gazettal

*The Food Standards Code is varied by -*

[1] *inserting immediately following Standard 2.6.3 -*

## *Standard 2.6.4*

# *Formulated Caffeinated Beverages*

**Purpose**

The purpose of this Standard is to regulate non-alcoholic water-based flavoured formulated caffeinated beverages that are manufactured for the purpose of enhancing mental performance.

**Table of Provisions**



## 1 Interpretation

In this Standard –

**caffeine** means all caffeine present from whatever source in a formulated caffeinated beverage.

**formulated caffeinated beverage** means a non-alcoholic water-based flavoured beverage which contains caffeine and may contain carbohydrates, amino acids, vitamins and other substances, including other foods, for the purpose of enhancing mental performance.

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

## 2 Composition

(1) A formulated caffeinated beverage must contain no less than 145 mg/L and no more than 320 mg/L of caffeine.

**Editorial note:**

Standard 1.3.1 (Item 14.1.3 of Schedule 1) regulates food additives for the purposes of this standard.

The addition of caffeine to formulated caffeinated beverages goes beyond a technological function under Standard 1.3.1 and, therefore, the permission for the addition of caffeine is located in this Standard rather than in Standard 1.3.1.

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

Table to subclause 2(2)

| Column 1 | Column 2 |
|---|---|
| **Substance** | **Maximum amount per one-day quantity** |
| Thiamin | 40 mg |
| Riboflavin | 20 mg |
| Niacin | 40 mg |
| Vitamin $B_6$ | 10 mg |
| Vitamin $B_{12}$ | 10 µg |
| Pantothenic acid | 10 mg |
| Taurine | 2000 mg |
| Glucuronolactone | 1200 mg |
| Inositol | 100 mg |

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

**Editorial note:**

Other foods such as herbal substances may be added to formulated caffeinated beverages unless this is proscribed elsewhere in the Food Standards Code.

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

## 3 Labelling

(1) The label on a package of formulated caffeinated beverage must include declarations of the average quantities, per serving size and per 100 mL of –

(a) caffeine, expressed in milligrams; and
(b) the substances listed in column 1 of the Table to subclause 2(2) expressed in the units included in column 2 of the Table.

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

**Editorial note:**

An example of the placement of the declarations required under subclause 3(1) adjacent to or following a nutrition information panel as permitted under subclause 3(2) is set out below.

| **NUTRITION INFORMATION** | | |
|---|---|---|
| Servings per package: (insert number of servings) | | |
| Serving size: 250mL | | |
| | Quantity per Serving | Quantity per 100 mL |
| Energy | kJ (Cal) | kJ (Cal) |
| Protein | g | g |
| Fat, total | g | g |
| -saturated | g | g |
| Carbohydrate, total | g | g |
| -sugars | g | g |
| Sodium | mg (mmol) | mg (mmol) |
| **COMPOSITION INFORMATION** | | |
| Caffeine | mg | mg |
| Thiamin | mg | mg |
| Riboflavin | mg | mg |
| Niacin | mg | mg |
| Vitamin $B_6$ | mg | mg |
| Vitamin $B_{12}$ | µg | µg |
| Pantothenic acid | mg | mg |
| Taurine | mg | mg |
| Glucuronolactone | mg | mg |
| Inositol | mg | mg |

(3) The label on a package of formulated caffeinated beverage must include advisory statements to the effect that –

(a) the food contains caffeine; and
(b) health authorities recommend limiting caffeine intake; and
(c) the food is not recommended for –

(i) children; and
(ii) pregnant or lactating women; and
(iii) individuals sensitive to caffeine.

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

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

(5) Where a formulated caffeinated beverage is not required to bear a label pursuant to clause 2 of Standard 1.2.1, the advisory statements under subclauses 3(3) and 3(4) must be -

(a) displayed on or in connection with the display of the food; or
(b) provided to the purchaser on request.

**Editorial note:**

The advised one-day quantity is calculated from the permissions in the Table to subclause 2(2) as it relates to the concentration of substances in the product. The substance that yields the lowest equivalent amount will determine the advised consumption limit.

For example:

| Column 1 | Column 2 | Column 3 | Column 4 |
|---|---|---|---|
| Product X formulation | Concentration (mg/L) | Maximum permitted one-day quantity (refer to Table to subclause 2(2)) | Equivalent amount of product X (mL) |
| Riboflavin | 30 | 20 | 666 |
| Niacin | 80 | 40 | 500 |
| Pantothenic acid | 15 | 10 | 666 |
| Taurine | 2000 | 2000 | 1000 |

The equivalent amount in Column 4 is calculated as $\frac{\text{Column 3 x 1000}}{\text{Column 2}}$

In this example niacin presents as the most limiting substance, and therefore, the advised consumption limit for product X would be 500mL. If product X is packaged in 250mL cans, the advised consumption limit may also be expressed as 'two cans' – for example –

"consume no more than 500mL per day" or "consume no more than two cans per day".

(6) A formulated caffeinated beverage is not a 'claimable food' in Standard 1.3.2.

(7) The label on a package of formulated caffeinated beverage must not include declarations of the quantities of vitamins present in the food expressed as a proportion or multiple of the -

(a) Recommended Dietary Intakes; or
(b) Estimated Safe and Adequate Daily Dietary Intakes;

of that vitamin.

[2] *omitting paragraph 2(2)(l) of Standard 1.2.1, and substituting –*

(l) subclause 3(2) of Standard 2.6.3; and
(m) subclause 3(3) of Standard 2.6.4; and
(n) subclause 3(4) of Standard 2.6.4.

[3] *inserting into the 'Purpose' in Standard 1.3.2, immediately after the words* Standard 2.4.2 –

, the addition of vitamins to formulated caffeinated beverages in Standard 2.6.4

**ATTACHMENT 3**

**SUMMARY OF SUBMISSIONS RECEIVED AT INQUIRY**

**A394 – FORMULATED CAFFEINATED BEVERAGES**

1. Introduction

Thirty-seven submissions to A394 were received, 15 from industry, 16 from consumers and public health professionals and six from government organisations. The majority of submissions were from Australia, and New Zealand was also represented with 9 submissions. There were 3 international representations; these were from the US Department of Agriculture, Professor James of Ireland and a submission by Weekes Preston on behalf of the Austrian applicant.

2. Issues raised

In order to provide a contextual focus, the issues raised have been summarised according to the Section 10A objectives of the *ANZFA Act 1991* as they bear relevance to this proposal, these are: a) protection of public health and safety; b) provision for consumer information; and c) consideration of potential barriers to trade. This latter aspect includes issues relating to promotion of fair trading and international harmonisation.

Consideration has also been given to more detailed comments relating to the drafting, this includes specific drafting notes and views on the terms and definitions used, and technical aspects of production of Formulated Caffeinated Beverages (FCBs) including packaging and marketing.

Summarised comments on these issues as presented by submissions are provided below.

*2.1 Substantiation, safety and compositional issues*

There were concerns regarding a lack of 'hard data' for either the safety or efficacy of a number of the substances added to FCBs. Questions were raised as to why the substances need to be present, especially if safety has not been clearly demonstrated and if the benefits were only 'perceived' rather than actual. The omission of Professor James dissenting report from the Expert Working Group on Caffeine was noted, along with his concerns regarding caffeine and the risks from long-term caffeine exposure at any level.

**Caffeine**

Caffeine was raised by a number of submitters in relation to a range of proposed detrimental health effects such as sleeplessness, anxiety, osteoporosis, mental illness including depression, compromised iron and zinc absorption during pregnancy, harm to the unborn child, newborn and nursing babies, cardio vascular disease and anaemia. Furthermore, concerns were also expressed regarding considered detrimental effects when caffeine is taken in conjunction with alcohol, nicotine, complementary medicines and/or illicit drugs. It was also noted by one submitter that caffeine meets some of the WHO and American Psychiatric Association criteria for a drug of dependence, and that further research is required to examine the dependency effects in children.

The NSW Parents' Council noted that health and food professionals do not seem sufficiently aware of the physical and mental problems associated with caffeine use, especially by school-age children and that these dangers were not fully covered by the Full Assessment report. They were also concerned that children use such substances inappropriately to give themselves an 'edge'. Dr Rosemary Stanton was quoted suggesting caffeine causes insomnia and possible hyperactivity in children and could trigger problems in children with heart abnormalities. Another view was also quoted in relation to the thirst disorders created by ecstasy use; the implications were that beverages [such as energy drinks] may be consumed in large quantities instead of water, thereby exacerbating the health problems associated with ecstasy use.

The proposed maximum and minimum levels for caffeine were considered by a number of submitters. Except for those opposed to caffeinated beverages *per se*, the maximum limit was widely accepted. There was however, considerable comment on the proposed minimum concentration of caffeine, primarily from the Australian Soft Drink Association (ASDA) and those supporting its submission. These submitters argued that the minimum level should be removed allowing for greater innovation of products and the flexibility to produce non-caffeinated 'energy drinks'. It was also noted that by maintaining the caffeine requirement a number of products already on the market would be unable to comply with the proposed standard. The MOH also supported the removal of the lower caffeine limit. Professor James expressed the view that minimum levels of caffeine were untenable because of the long-term health implications of caffeine intake at any level.

On a more technical note it was identified that the means of limiting added substances was inconsistent with caffeine being limited per volume (i.e. mg/L) whereas, other substances are per daily consumption.

Most submitters noted the current market presence of caffeine in various forms; their points related more to the desire to avoid a further proliferation of caffeinated products, particularly in forms which are seen to be appealing to children.

A further point made was that the safety assessment should also take into account possible synergistic effects of all 'active' ingredients, and possible effects if taken in conjunction with alcohol and/or illicit drugs.

**Other nutritive substances**

Caffeine was clearly the main substance of concern from most submitters however, comments were also made in relation to the glucuronolactone, inositol, taurine and vitamin B6 contents of FCBs. These concerns were primarily from the point of view of requiring better scientific justification for safety, particularly in relation to the [high] quantities of the substances present, and efficacy. One submission suggested permissions for glucuronolactone, inositol and taurine should be deleted and another, that vitamins C and E and folic acid should be prohibited on the basis that they give the misleading impression the products are vitamin supplements.

One submitter also raised the issue of product stability and whether the shelf-life of the active ingredients is adequate to support claims associated with the product. It was noted that this aspect relates to potentially false and misleading claims.

The more general suggestion was also made that permissions should be based on levels well below the acceptable intakes, as consumers may not see the label information e.g. where energy drinks are purchased as mixed drinks in a public bar.

There were also a number of submissions for increased permission for added substances and in particular, that non-caffeinated beverages also be considered. A submission on behalf of the applicant provided a review on the health effects of niacin that suggests the daily consumption limit for niacin as proposed could safely be increased to at least 40mg. This approach was contrasted by another industry submission that suggested the niacin level was [too] high insofar as, it appeared to exceed the United States recommended daily upper limit (USRDI) for niacin intake by 14-18 year-olds and could be readily exceeded by contribution from other dietary sources. Furthermore, an inconsistency of approach was noted whereby, the proposed niacin maximum intake represented 100% of the upper USRDI but vitamin B6, for example, was just 10% of the upper USRDI of niacin.

In other submissions it was suggested that the proposed maximum limits for riboflavin, pantothenic acid, vitamins $B_6$ and $B_{12}$ should be removed and that permissions should be extended to include vitamins A,$B_1$, C and E such that more flexible formulations can be produced for both caffeinated and non-caffeinated beverages. Substantiating data were not provided to support these requests. Taisho Australia noted that the core vitamins and minerals potentially of most benefit were not included, one of the most appropriate being thiamine for which some supporting documentation was provided. An alternative proposal was that limits on nutritive substances should be in accord with other permissions such as those given in Standard A9 (Volume 1 of the Food Standards Code (FSC)), with maximum levels no greater than the nationally recommended dietary intakes.

**Non-nutritive sweeteners**

The Food Technology Association of Victoria submitted that non-nutritive sweeteners should also be permitted albeit, recognising the argument for carbohydrate as source of energy. However, it was considered by the submitter that the carbohydrate content is not integral to ‘energy’ provision as this purpose would appear to be satisfied from increased levels of caffeine, vitamins and other biologically active substances.

**Herbal substances**

Clarity was sought regarding the permissions or otherwise for herbs or herbal extracts including St John’s Wort, Echinacea, Gingko and Ginseng to be added to FCBs. It was suggested by the Complementary Healthcare Council that herbals should be permitted at traditional food use levels whereas, if higher amounts were included in the formulation to achieve a therapeutic purpose these products would be more appropriately regulated as therapeutics.

**Consumption data**

Comments were made on the lack of consumption data for FCBs, particularly in relation to children. An indicative summary of further consumption data was provided by the applicant that suggests lower intakes by regular users than were presented in the Full Assessment report. These new data suggest regular consumers, aged 15-50 years-old, average 110mL/day whilst high consumers average 250mL/day.

The MOH also indicated that some preliminary data would soon be available on 'energy drink' consumption from a pilot survey of New Zealand children.

Consumption by children was by far one of the greatest concerns expressed by submitters in relation to this proposal. The submitters who directly discussed this aspect were most concerned about the demonstrated and also potentially unknown effects of caffeine on children, in conjunction with the ready accessibility and observed appeal of the product to children.

This discussion also raised comments on an appropriate age by which to define 'children' for the purposes of these beverages. Suggestions put to ANZFA from submissions and other discussions have proposed 12 years, 15 years, 18 years or 'school-age' children with most views focussing on 15 years or 18 years. Professor Kim Oates of The Children's Hospital at Westmead states that if these products are to be available, they should clearly state they are not suitable for children under 15 years of age. Whereas, 18 years was supported by the State health department in Queensland, the New South Wales Parents Council and Public Health South New Zealand. It was also noted that children having proof-of-age cards could aid this latter approach.

## 2.2 Consumer information

Discussion on consumer information for FCBs related to the proposed labelling information. This includes advisory statements including 'dosage' or intake information, compositional labelling, nutrition labelling including nutrition claims and the nutrition information panel, and health and related claims.

**Advisory statements**

The advisory statements were well supported by all submitters who commented on this aspect although, the US Department of Agriculture considered that compositional limits would be a more direct and preferable approach. It was also observed by some, that advisory statements will not be a sufficiently effective risk management approach i.e. 'better protection' is needed, and the statements may even have the reverse effect of adding greater appeal to children. Anti-smoking label warnings were used as an example of unsuccessful advisory information.

Suggestions made to enhance the proposed advisory statements included:

- advising limits on daily caffeine consumption;
- including pregnant and lactating women in 'not suitable for - ';
- strengthening of language and format e.g. "**This food should not be consumed by..**" (in bold, 5mm type);
- advising consumption limits to distinguish between adults and children;
- [more] clearly indicating non-suitability for children e.g. specified type size, format and prominence;
- specifically identifying caffeine from guarana; and
- carrying warning statements for guarana, as required by therapeutics.

The use of a pictogram e.g. cup of coffee to indicate caffeine content was not widely supported due to being insufficiently definitive and potentially confusing.

**Intake information**

The proposal to provide advised limits on daily consumption was widely supported by all stakeholders, but considered too prescriptive by some and insufficiently informative by others. Those considering it too prescriptive referred primarily to the limitations resulting from the limits on niacin intake at 35mg/day. It was noted that this would translate to an advised consumption limit of 1.75 (250mL cans) per day. The submitter proposed that the niacin limit be increased to 40 mg /day, which would translate to two 250mL cans per day.

Another suggestion was to advise consumption on the basis of 'cans per day' rather than millilitres.

Those submitters wanting more information suggested that daily caffeine intake should also be advised, and that recommendations should relate to adults and children separately.

All submissions on this issue agreed that an advised daily intake or 'dosage/usage' was inappropriate (i.e. advice to the effect that this amount should be consumed in order to achieve maximum effect) however, it was also noted that 'daily consumption limits' as proposed at Full Assessment did not sufficiently differentiate from the dosage approach, and that the wording should be changed to more clearly reflect that the amount should not be exceeded.

**Compositional labelling**

No comments were received specifically on compositional labelling except to state that labelling should clearly indicate the contents and that sugar content (as well as total carbohydrate) should be declared. Rather, most comments focused on nutritional labelling as discussed below.

*Nutritional labelling – panel and claims*

Views on the merits or otherwise of including nutritional labelling on these products were divided. Consumers and public health professionals, and the MOH, supported the proposal to prohibit this type of labelling on the basis that it sends misleading messages to consumers in relation to the role of the product in normal dietary intake, particularly as these products contain substantial amounts of added nutritive substances thereby, indicating they have a health-promotional role. It was considered that this potential misperception is exacerbated by the unproven nature of the physiological role these products may play.

Similarly, consumers and public health professionals agreed that claims relating to added nutritive substances expressed as a percentage of nationally recommended or estimated dietary intakes (e.g. %RDI, %RDA or % ESADDI) were inappropriate again, on the basis of giving potentially misleading messages and indications that these beverages could be construed as vitamin supplements or otherwise nutritionally beneficial.

Contrary views were provided by the US Department of Agriculture, industry representations and one State health department. The US Department of Agriculture noted that the absence of nutrition information would be incompatible with US requirements and furthermore, that complete nutrition information is necessary and not an endorsement of 'healthy'. It was further suggested by another submitter that the provision of such information would be appropriate for demonstrating the lack of nutritional value inherent in these products.

Representations from a number of non-alcoholic beverage manufacturers and their representative organisation questioned the reasoning for prohibiting a nutrition information panel. They noted the inconsistency of this approach with the recent introduction of mandatory provisions for nutrition information for other non-alcoholic beverages (as per Standard 1.2.8 in Volume 2 of the Code). It was also noted that there was 'no point' in adding nutritive substances if their presence could not be claimed.

*Health and related claims*

The validity and appropriateness of a number of claims currently used in the marketing of FCBs was questioned by a number of submitters. It was considered that some are either difficult to verify or misleading, and the point also made that the withdrawal symptoms of caffeine are in fact, contrary to the promotional indications of energy drinks.

There were views that health and related claims should not be allowed, or more generally, agreed that any health and related claims should be subject to the proposed outcomes of proposal P153. The point was also made that health claims will 'be required' in order to explain and promote these products. One suggestion was that ANZFA should mandate statements that are allowed, such that consumers understand the role of energy drinks and not be misled.

## 2.3 Barriers to trade

The applicant noted that the use of the name 'Formulated Caffeinated Beverages' would constitute a barrier to trade. It was also emphasised by a number of manufacturers and the ASDA that a standard restricted to caffeinated beverages, or one which only addresses formulations including >145mg caffeine/L, will stifle innovation and will not ease current inequities in trade as a number of their formulations would still not be covered. It was noted that, as long as the Trans Tasman Mutual Recognition Arrangement is in place, New Zealand and other international manufacturers will have an advantage over Australian industry. Furthermore, a number of products currently sold on the international market will not be able to be produced in Australia. One submitter also stated that these issues should be dealt with now, rather than waiting for the broader dietary supplement review.

ASDA further identified that if added herbal substances such as ginkgo and ginseng are to be seen as novel foods, this would require pre-assessment which would mean reformulation or removal from the market.

The US Department of Agriculture noted that the product would be inconsistent with the US thereby, creating marketing difficulties.

As an alternate view, the NSW Parents Council considered that issues in relation to trade barriers are in effect 'red herrings' as the United Nations Convention on the Rights of Children would take precedence over any trade agreements.

## 2.4 Terms and definitions

**Formulated caffeinated beverages**

*FCBs are defined in the Full Assessment report as:* Non-alcoholic water-based beverages which contain caffeine and carbohydrate and may contain amino acid(s), vitamin(s) and other substance(s) (including other food(s)) for the purpose of providing real or perceived enhanced physiological and/or performance effects.

*Support for this name was divided between those who considered it an appropriate descriptor, and those who found it unwieldy, too restrictive and/or not familiar with the general public. The applicant noted it was too long, unwieldy, too regulatory, not sufficiently definitive and has no international precedent and, that a prescribed name is not necessary [as was implied in the Full Assessment report]. It was also suggested that the word psychological be added to the above definition such that it reads: ….…* for the purpose of providing real or perceived enhanced physiological, psychological and/or performance effects.

A number of manufacturers suggested the word 'caffeinated' be removed or qualified with '*may contain caffeine'* to create wider scope for other formulated beverages. ASDA and associated industry submissions strongly opposed the term and associated definition on the basis of its restrictive nature [to caffeinated beverages]. Alternative names suggested by various submitters were 'Formulated Stimulant Beverages', 'Energy Drinks', 'Formulated Beverages', 'Formulated Water Beverages". This latter suggestion was accompanied by the view that these beverages could be regulated as exceptions to the general vitamin and mineral permissions. Furthermore, there should not be any implications that they provide energy beyond other [soft drink-type] beverages. The State health department in Queensland expressed concern that this definition may set a precedent for similar fortification of other foods not generally considered conducive to good health and/or the addition of caffeine to other soft drinks.

Support for 'energy drinks' was largely based on the current familiarity of the term. Another manufacturer also maintained the term 'energy drinks' is not misleading as the beverages contain sugar, which metabolises to energy. The MOH suggested the term 'formulated caffeinated beverages' be replaced with 'energy drinks' as this term is more commonly used and accepted. The term 'stimulant' beverage was not supported b/c of possible links with drugs and the associated effects. It was also noted that ANZFA's suggested definition may encourage therapeutic use or claims. The suggested alternative was: *Energy drinks are non-alcoholic water –based beverages which contain carbohydrate and may contain caffeine, amino acids, vitamins and other substances (including other foods) for the purposes of providing real or perceived nutritional support for performance.*

Comments in support of the term and definition noted that differentiation between these beverages, and sports and electrolyte drinks, was appropriate and that development of a particular standard afforded a means of controlling composition, marketing and labelling of the product.

**Functional products/foods**

*This term was defined in the Full Assessment report as:* Formulated products, similar in appearance to conventional foods, which have been modified beyond the provision of simple nutrient requirements for the purpose(s) of achieving real or perceived physiological and/or performance effects. *There were a variety of views as to both: the proposed working definition, and whether FCBs are appropriately considered as functional foods.*

*The applicant suggested that the word psychological also be added to this definition such that it reads: ……* for the purpose of achieving real or perceived enhanced physiological, psychological and/or performance effects.

The term and development of this category of products was full supported by ASDA. There was also considerable support for both the creation of this category and the term used, although it needs to be clarified as to whether the category should be referred to as 'functional products' or ' functional foods'.

Concerns regarding the definition particularly focused on the word 'perceived'. Three submitters considered this term is unacceptable, and has no place is this context as it undermines the scientific rationale that supports the rest of the FSC. It was viewed that formulations must be rational and substantiated. It was also noted that health claims are integral to this category and to have a product defined in a capacity for which it cannot legally advertise is confusing and may exacerbate non-compliance.

The Food Technology Association of Victoria suggested that functional foods be addressed in a separate document as it was considered that FCBs are not designed or intended to be functional foods. They also noted that the term 'perceived' is open to interpretation and should be debated.

The National Council of Women of Australia (NCWA) suggested that *real or perceived physiological and/or performance effects* be replaced with *enhanced psychoactive and/or performance effects* which, they considered, would also have the effect of efficacy having to be established prior to marketing. There was also the view that the term 'functional' can be problematic as all foods can be seen to be effectively functional. The NCWA did not support the creation of a special standard to be later expanded for a wider range of dietary supplement or functional products.

The MOH noted that functional foods need to be clearly distinguished from special purpose foods, but suggested the term 'supplemented foods' may be more appropriate as 'functional ' implies functions beyond normal and some of these foods may only contain extra nutrients. The Peters and Brownes Group considered this category should also accommodate formulated supplementary and functional dairy products and that dietary supplements need to be clearly differentiated from formulated supplementary foods.

**Children**

A number of submissions noted the need to define an age for 'children' in the context of advisory statements for unsuitability of the product. This aspect has been discussed earlier under issues relating to public health and safety (refer section 3.1 of this document).

## 2.5 Marketing and packaging

There were a number of comments on the way FCBs are currently marketed and packaged and suggestions for future approaches. The comments were largely based on concerns regarding availability and appeal to children, and the view put that the applicant's contention that the product is not marketed at children is not actually meaningful. It was noted that despite (or even because of) the advisory statements, marketing of these products will encourage consumption by some children and adolescents. Furthermore, the products are freely available to children and often accompanied by appealing advertising with no mention of caffeine. It was also noted that the current and recent media attention on 'energy drinks' has inadvertently aided their promotion to young people.

Suggestions received for managing access to children include:

- any attempts to resemble soft drinks should be avoided;
- monitor distribution through vending machines with sites not being close to schools; and
- avoid 'slogans' appealing to stressed or depressed young people such as 'vitalise body and mind' or suggested enhancement of performance effects.

It was also suggested that another approach would be to limit container size however, it was recognised that this approach may be problematic due to potential restrictions on trade and competition policy guidelines.

## 2.6 Drafting notes

Some submissions made specific comments relating to the drafting as it supports the proposals given in the Full Assessment report. These largely related to matters of clarity and were as outlined below.

- Mandatory advisory statements also need to be in Standard 1.2.3 and appropriately cross-referenced.
- The declaration required by subclause 3(1) does not put levels of nutritive substances into context –it would be useful for consumers to know these are [high] levels.
- Editorial note on page 18 stating 'an example of declaration required by 3(1) is below' should refer to subclause 4(1) in respect of volume 2 of the FSC.
- These beverages could alternatively be accommodated by the non-alcoholic beverage standards (04; 2.6.2) – in which case these standard would need increased permissions for caffeine and other added substances.
- Does the purpose clause of Standard A9 need to be amended to include proposed draft Standard R11?
- The definition of one-day quantity sounds like a dosage – this should be changed to clearly indicate it is an amount not to be exceeded. It would also be useful to have an editorial note explaining how the one-day quantity is derived.
- Declaration of caffeine should include amount from guarana.
- Manufacturers need to be provided with information as to how to calculate daily consumption limits.

**A U S T R A L A S I A N**
**SOFT DRINK ASSOCIATION LTD**
ABN 12 115 440 166 ACN 003 048 011

Project Manager - Application A394
Australia New Zealand Food Authority
PO Box 7186
Canberra MC ACT 2600

18th June 2001

Dear Jane,

Application A394 – Final Submission

On behalf of ASDA I would like to submit the following comments to your full assessment's stakeholders comments summary paper in regards to Application A394 - Formulated Caffeinated Beverages.

**Potential Exposure of Caffeinated Beverages to Children**

In response to the concerns raised, the Industry has adopted the following policy:

*"The Australasian Soft Drink Association Ltd whilst recognising that there are no issues of health and safety associated with the normal consumption of 'formulated caffeinated beverages' (energy drinks) by children, nevertheless recognises that these products are formulated and marketed as adult non-alcoholic refreshments and therefore recommends to all members that Formulated Caffeinated Beverages (Energy Drinks):*

- Be labelled as not "recommended for children"
- Not be sold via school canteens or in vending equipment located on school premises

In adopting that policy, the Industry recognises that it has no control over the action of non-members and that the final responsibility for what is sold in school canteens clearly rests with school principals and school boards.

**Advisory Statements**

The Industry does not believe that there is any need for the Standard to reflect any mandatory requirement other than the provision of the above advisory statement on labels.

The issue of definition of "children" by way of an expressed age on labels as part of the advisory statement is strongly opposed by Industry. Any age chosen would be arbitrary and would not be based on sound scientific reasoning. In opposing this suggested provision we point out that:

- Children achieve varying levels of maturity at different ages. Parental responsibility in identifying these developments should be paramount in the advice and direction that they provide to their children about what they eat, drink, watch and read.
- If the suggested age is based on the possible physiological effect of caffeine, we again point out the large variations in children's body weights that would render such a suggestion meaningless.

Whilst in no way acceding to the recommendation that an age should be specified, we suggest that in the event that the Authority feels compelled, for whatever perceived reason to do so, that a more rational basis be found. In that event, we suggest that age 12, would be the most appropriate, given that this is the age when children finish primary and commence high school.

This age is also that generally regarded as the dividing point between childhood and adolescence. The suggestion of 15 or 18 as suitable ages should be immediately discarded. In support of this, we point out that current legislation with regards to the legal sale of tobacco products is 16.

The suggested *"strengthening"* of the advisory statements by use of words such as *"This food should not be consumed by.."* are similarly opposed as being unnecessary and not based on any scientific evidence that the consumption of energy drinks by children represents a health & safety concern. We point out that there has never been any suggestion, nor do we suggest that there should be, that products such as coffee and tea or for that matter, coffee flavoured milk carry such advisory statements. We therefore see no reason whatsoever for this proposal.

The industry also does not believe that there should be any specific requirements for font types and size in relation to mandatory advisory statements. Energy drinks should not be subjected to any additional requirements that are not already covered in standards 1.2.1 1.2.3 or 1.2.9 of the Food Standard Code as there is no health and safety issue involved with the normal consumption of these beverages.

The issue of caffeine consumption by pregnant and lactating mothers is currently appropriately dealt with by the medical profession as part of general education of pregnant women. We suggest that food labels clearly displaying the presence of caffeine in the product represent sufficient advice. Food labels, in our view, are not the appropriate means for delivery of such individual specific information. We again point out that there no suggestions for similar warnings on other caffeinated beverages such as coffee and tea.

We reiterate that this debate is largely based on anecdotal and perceived anticipated possible negative outcomes, rather than any demonstrable scientifically based evidence. Caffeine has been safely consumed by children via chocolate, chocolate and coffee flavoured milks and in many cultures, coffee and tea, for centuries.

### Other Substances

ASDA fully supports the increase of niacin levels from the proposed level of 35 mg to 40 mg / day, and the addition of thiamin to the standard. The industry also believes that there needs to be a clarification on which herbal substances can be added to the beverages and in what concentrations.

### Prescribed Name

The formerly proposed prescribed name (Formulated Caffeinated Beverages) is viewed by the industry as being overly prescriptive, unfamiliar to the consumer and one that does not fully encompass the variety of products that are already on the market. The industry therefore strongly urges that no prescribed name be used in order to align the proposed standard with the rest of the Food Standards Code (vol. II)

### Nutrition Labelling

As mentioned in earlier correspondence it is unclear to ASDA members as to why ANZFA propose to prohibit the use of Nutrition Information Panels (NIP) from the labels of these beverages, particularly in light of the recent legislation established in order to make it mandatory for all food and beverages in the market place to carry such panels. ASDA does not see the logic in exempting NIPs for these beverages particularly when a detailed ingredient table is to be required in any case.

The exclusion of NIPs from 'Energy Drink' labelling would mean that the inclusion of this category of beverages within a functional foods standard would be a complete contradiction and would show inconsistency within the new food standards. It would also mean that there would be less nutritional and dietary information available to consumers.

The arguments against the provision of NIPs for energy drinks, would be just as valid as those used against the provision of NIPs in soft drinks. Arguments which the Authority rejected.

### Definitions

- **Formulated Caffeinated Beverages**
    - ASDA fully supports the original definition proposed by ANZFA, that being:

*"Non-alcoholic water-based beverages which contain caffeine and carbohydrate and may contain amino acid(s), vitamin(s), and other substance(s) (including other foods(s)) for the purpose of providing real or perceived enhanced physiological and/or performance effects."*

- The inclusion of the word "psychological" to the standard is deemed by the industry as being unnecessary as the definition already contains the word “perceived” which in our opinion adequately covers “psychological” benefits.

- **Functional Beverages**

  - As with the energy drinks definition, the industry does not support the addition of psychological to the definition as it is considered superfluous.

**Mixed Foods**

ASDA strongly opposes the addition of any statement that prohibits the mixing of energy drinks with a standard soft drink or for that matter any other food. Industry believes that this may set an unwarranted precedent for future applications (i.e. caffeine in carbonated soft drinks). Although it is clear to both ANZFA and the industry that the two issues are clearly different, (i.e. the addition of caffeine to regular soft drink is purely for organoleptic reasons, whilst in energy drinks it is used to boost physiological performance) it may not be so clear to less informed groups which may see it as another negative comment about caffeine's safety.

The addition of this prohibition to the standard also clearly contradicts the proposed definitions which states:

*"Non-alcoholic water-based beverages which contain caffeine and carbohydrate and may contain amino acid(s), vitamin(s), and other substance(s) (including other foods(s)) for the purpose of providing real or perceived enhanced physiological and/or performance effects."*

The industry promotes energy drinks in a niche market and it does not serve either industry or the consumer any purpose in diluting the product with regular soft drink as it would reduce the physiological benefits gained from consuming the product, and it would devalue the products’ image and ultimately the market.

Should you require clarification of any of the comments listed above, please contact the undersigned or Mr. Tony Gentile, Chief Executive, ASDA on 02 9344 3522.

Best Regards,

Adam Franklin
**Science and Regulatory Affairs Officer ASDA**

**ATTACHMENT 4**

## AMENDED REGULATION IMPACT STATEMENT

The *Food Standards Code* and the New Zealand *Food Regulations 1984* do not contain provisions to allow the sale of formulated caffeinated beverages (FCBs). However the provisions of the New Zealand *Dietary Supplement Regulations 1985* (NZDSR) do allow for such formulations and on this legal basis these beverages are sold in New Zealand from imports and domestic production. While the FCBs cannot be produced in Australia, they can be imported from New Zealand, under the Trans Tasman Mutual Recognition Arrangement (TTMRA), but not directly from any other country.

FCBs have been sold in Australia for the past three years, and the market is currently valued at $150 million. It is expected to double again within two years to $300 million. This would be less than 5% of the total FCBs / soft drink market.

FCBs typically contain a mixture of vitamins and other biologically active substances, caffeine equivalent to a strong cup of coffee and some contain herbal substances. They are largely marketed to the 'night club scene', and more recently broadened to daytime 'pick-ups' as a substitute for cup(s) of coffee.

The applicant states that the target market in Australia [and internationally] is adults and that the product is not [directly] marketed at children.

The *Food Standards Code* currently consists of Volumes 1 and 2, where Volume 2 is the new Joint Code. As Volume 1 of the *Foods Standards Code* is time limited, discussions concerning possible regulation within the *Food Standards Code* have been limited to within the context of Volume 2 only.

### 6.1 The Problem

Three sets of problems arise with this application. First, there is the problem of consistency between domestic and international food standards, particularly between Australia and New Zealand. Second, there are the risks that FCBs may pose to public health and safety, when consumed to excess and / or by children. Third, there is genuine confusion amongst consumers, where FCBs are mistaken for soft drinks or 'health drinks'.

The extent of the risks to public health and safety would seem small at present, given the small size of the market for FCBs. However the rapid growth in the Australian market to date, and the rapid growth envisaged in the immediate future, will amplify the risks to public health and safety. Potentially, these risks could be high particularly if those other than the intended target groups use the products.

### 6.2 Objectives

The objectives for this application are:

**1.** To protect public health and safety in the consumption of FCBs, particularly by promoting safe levels of consumption and ensuring that children do not consume them.

**2.** To develop consistent food regulations applying to FCBs between Australia and New Zealand.

**3.** To provide information to consumers to enable them to make informed choices about the consumption of FCBs.

### 6.3 Options

There are five options for the regulation of FCBs. These are:

**Option 1** **No permission within the *Food Standards Code* (the status quo) but continued operation of the NZDSR and TTMRA**

**Option 2** **Full regulatory provisions within the *Food Standards Code***

**Option 2a** **Full regulatory provisions within the *Food Standards Code*, complemented by support from jurisdictional policies**

**Option 3** **Part regulation in conjunction with self-management by industry (co-regulation)**

**Option 4** **No permission within the *Food Standards Code* and no permissions through the NZDSR**

### 6.4 Impact Analysis – Affected Parties

The parties affected by this application are: **consumers**, including children, the target market of adults, and people sensitive to caffeine; **industry**, including New Zealand manufacturers and exporters to Australia, multi-national manufacturers, and Australian manufacturers capable of manufacturing FCBs; **governments** of New Zealand, the States and Territories and the Commonwealth of Australia; and **public health** professionals.

### 6.5 Impact Analysis

***Option 1: Status Quo – do not permit FCBs to be manufactured under the Food Standards Code but continued operation of the NZDSR and TTMRA***

**Description**

The current prohibition on the manufacture of FCBs in Australia would be retained. FCBs would continue to be manufactured in New Zealand under NZDSR and able to be exported into Australia for sale under TTMRA. Products manufactured in other countries would be able to be imported into Australia *via* New Zealand.

**Government**

*Advantages*

- No change required to enforcement in both Australia and New Zealand.

*Disadvantages*

- Continued discrepancy between Australia and New Zealand food law.
- Increased political lobbying and pressure regarding inequality of manufacturing opportunities for Australian industry.

**Consumer/Public Health**

*Advantages*

- Ready availability and choice of FCBs to interested consumers.

*Disadvantages*

- Continuation of apparent consumer confusion over the marketing of FCBs in Australia [as dietary supplements] when the product itself is not permitted [for manufacture] in Australia.
- Continued inconsistencies in labelling provisions between food sold under different regulatory regimes.
- Increasing risks to public health and safety, as the Australian market for FCBs expands, of excess consumption or consumption by children.

    - According to the NZDSR, maximum consumption of the applicant's product is 5 cans per day. This information has been misinterpreted by some consumers, as meaning that 5 cans are necessary to have the desired effect and particularly if consumed in a short timeframe. Such high short-term consumption poses risks to many consumers, particularly children, pregnant or lactating women or those whose are caffeine-sensitive.
    - Children are at risk, with adverse reactions possible at low levels of consumption because of their relatively lower body weights and because they are physiologically unprepared for an unaccustomed dose of caffeine, a powerful stimulant. Even where adverse reactions do not occur, moderate consumption can affect concentration. This aspect may be of particular concern within the school context.

- Lack of competition between Australia and New Zealand in the supply of FCBs, resulting in higher prices.

**Industry**

*Advantages*

- New Zealand industry advantaged over Australian through the ability to sell product in both countries and internationally with no Australian competition.

*Disadvantages*

- Australian industry severely disadvantaged by not being able to manufacture and directly import FCBs in Australia.

- Overseas industry unable to import directly into Australia and must enter product via New Zealand.

*Conclusion*
This option does not achieve the objectives. Food regulations remain inconsistent between Australia and New Zealand. Risks to public health and safety continue and will increase, while information for consumers to make informed choices is inadequate. The disadvantages associated with these issues are significant, while the advantages of this option are very limited. Overall this option is not supported.

***Option 2 Full regulatory provisions within the Food Standards Code***

**Description**

The provisions within the *Food Standards Code* would be amended in order to provide permission for manufacture and import of FCBs under food regulation in both Australia and New Zealand. This would create provisions for the labelling and composition of FCBs within Volume 2 of the *Food Standards Code* and ultimately replace the current provisions for FCBs within the New Zealand *Dietary Supplement Regulations 1985.*

**Government**

*Advantages*

- Harmonised food standards ensuring consistency of regulatory approach between trading partners.

*Disadvantages*

- Any enforcement burden and costs to Australia arising from implementation of an additional standard, but expected to be small.

**Consumer/Public Health**

*Advantages*

- More products available to interested consumers.
- Greater consistency in regulatory provisions for products sold as foods, promoting more reliable information to consumers and more effective choices by consumers.
- Tighter controls over composition and labelling requirements, providing more information to consumers and enhancing their confidence in the product.
- More information in the form of advisory statements.

*Disadvantages*
- The availability of products with intended functions beyond normal nutritive purposes and high level of caffeine, with health risks when consumed to excess and / or by children.

- According to the NZDSR, maximum consumption of the applicant's product is 5 cans per day. This information has been misinterpreted by some consumers, as meaning that 5 cans are necessary to have the desired effect and particularly if consumed in a short timeframe. Such high short-term consumption poses risks to many consumers, particularly children or those who are caffeine-sensitive.
- Children are at risk, with adverse reactions possible at low levels of consumption because of their relatively lower body weights and because they are physiologically unprepared for an unaccustomed dose of caffeine, a powerful stimulant. Even where adverse reactions do not occur, moderate consumption can affect concentration. This aspect may be of particular concern within the school context.

**Industry**

*Advantages*

- Australian industry able to compete equitably with New Zealand industry.
- Australia able to export directly to, and import directly from, international market.

*Disadvantages*

- Potential for reduced market innovation in New Zealand as food standard potentially more restrictive than current New Zealand dietary supplement regulations.
- Possible lower growth in exports from New Zealand when the Australian market is no longer protected from overseas manufacturers. However, New Zealand exports are not expected to reduce in absolute terms, because the rapidly expanding market in Australia can accommodate all suppliers.

**Conclusion**

This option achieves some of the objectives. It would promote consistency in food regulations between Australia and New Zealand. It would improve the quality of information about FCBs and enhance consumers' ability to make informed choices. It would address the risks to public health and safety through tighter controls over consumption and through labelling, but labelling on its own may not be sufficient to achieve the public health and safety outcomes of safe consumption. There are significant disadvantages from not fully achieving the public health and safety objective. However this option also offers significant advantages to responsible and informed consumers, to industry and governments. Overall this option could be a net-benefit to the people of Australia and New Zealand.

***Option 2a Full regulatory provisions within the Food Standards Code, complemented by support from jurisdictional policies***

**Description**

This option is the same as Option 2, with the addition of jurisdictional policies to direct marketing of FCBs away from outlets commonly frequented by children such as schools and associated activities such as sporting teams.

This option also would involve liaison with industry, retail affiliates, non-government agencies and governments' education departments to recommend that FCBs not be made available to students at school or participating in school activities. Investigation of an industry code of practice elicited mixed support and so was not pursued. The response from *Red Bull* is given at Appendix 1 to this Attachment.

**Advantages**

The advantages would be the same as for Option 2, with benefits to consumers, industry and government.

**Disadvantages**

The disadvantages would be substantially less than Option 2. The support from education departments, complementing a new standard, has high potential to fully achieve the public health and safety objectives, with a consequent reduction in qualifications and disadvantages of Option 2.

**Conclusion**

Option 2a meets all objectives and is clearly a net-benefit to the people of Australia and New Zealand.

***Option 3 Co-regulatory provisions through industry codes of practice***

*Description*
Volume 2 of the *Food Standards Code* would be amended to give positive permission for some aspects pertaining to regulation of FCBs such as compositional requirements, whilst other aspects e.g. labelling, would be encompassed by a voluntary code of practice within each country. Enforcement responsibilities would also be shared between government and industry.

**Government**

*Advantages*

- Fewer burdens than full regulation (but more than is currently the case for Australia).

*Disadvantages*

- Likelihood of continued discrepancies between Australia and New Zealand.
- The mix of government agencies and industry bodies that manage FCBs may cause confusion, lack of clarity about the regulatory objectives and lead to diminished public health outcomes.
- Little control over labelling of imports.

**Consumer/Public Health**

*Advantages*

- Increased range of products available for interested consumers.

*Disadvantages*

- Potential for increased range of FCBs on the market that may have been less exposed to scrutiny on their labelling aspects.

**Industry**

*Advantages*

- Less prescriptive than the full regulation of Option 2, resulting in lower compliance costs for business.
- Greater control over some aspects, such as labelling and enforcement.
- Can choose not to subscribe to code of practice.

*Disadvantages*

- Increased responsibility and costs for implementation, management and enforcement, although overall compliance costs would be less than Option 2.
- Potentially greater inequalities in trading as code of practice is voluntary and may also Volume 2 of the *Food Standards Code* differ between countries.
- Not all manufacturers are bound by code of practice.

**Conclusion**

Labelling is considered to be a key element in achieving public health and safety and consumer information objectives. The co-regulatory approach, which does not guarantee a uniform standard of labelling for Australia and New Zealand, involves governments accepting a high level of risk, where these objectives may not be achieved. While there are advantages to industry, primarily from low compliance costs, these are outweighed by disadvantages to consumers when the objectives are only partially achieved or not achieved. Overall this option is not supported.

***Option 4 No permission within the Food Standards Code and no permissions through the NZDSR***

**Description**

Under this option there would not be any explicit regulation of FCBs under food laws in either Australia or New Zealand. Although this would be an equitable situation, it also means the necessary permissions for addition of nutritive substances, e.g. vitamins, would not be available to manufacturers thus, the product could not be produced.

**Advantages**

Option 4 achieves harmonisation and fulfils public health and safety needs

**Disadvantages**

This option does not achieve the objectives of the application as the product would be unable to be manufactured or imported. Furthermore, amendments to, or repealing of, the NZDSR would be required.

**Conclusion**

Option 4 does not present as a viable alternative within the context of this application and has not been given further consideration. Option 4 is not supported.

### *6.6 Consultation*

See Section 3 of the main report.

### *6.7 Conclusion*

**Option 1**, the status quo, does not achieve any of the objectives of this assessment and is rejected. **Option 4**, is not a viable option and is also rejected.

**Option 3**, co-regulation that allows commercial freedom in labelling, could achieve the objectives but involves a high degree of risk that the labelling outcomes would not support the public health and safety or adequate consumer information objectives. Given the importance of labelling to achieving these outcomes, this risk is considered to be unacceptable. The disadvantages flowing from these circumstances could be high and outweigh the advantages of this option (mainly low compliance costs for industry). Option 3 is not supported.

**Options 2** (a new standard) and **2a** (a new standard complemented by an industry code of practice and support from government and non-government agencies) do deliver on all objectives and provide net-benefits to the people of Australia and New Zealand. The difference is that Option 2a provides a much higher assurance of public health and safety without adding any significant cost to industry. **Option 2a is preferred**.

### *6.8 Implementation*

Option 2a as outlined above describes regulation within Volume 2 of the *Food Standards Code* however, as a standard for FCBs does not currently exist it raises the question of 'where' within Volume 2 of the *Food Standards Code* FCBs are best located. As identified at Full Assessment and reiterated at Inquiry, FCBs do not fit within the policy parameters of Special Purpose foods. It is therefore considered they should not be contained within Part 2.9 of Volume 2 of the *Food Standards Code.*

At Full Assessment the draft standard was positioned as a new category at Standard 2.11.1. After further consideration this draft has been relocated to Standard 2.6.4 where it is now adjacent to other non-alcoholic beverage standards.

**APPENDIX 1 TO ATTACHMENT 4**

**EMAIL ADVICE FROM WEEKES PRESTON REPRESENTING RED BULL ON POSSIBLE CODE OF PRACTICE, RECEIVED 11 JULY 2001.**

11 July, 2001

Dear Janine and Jane

I refer to my telephone conversation with Jane of Monday 18 June 2001, and to the follow up emails and fax of Janine, in relation to a possible industry Code of Practice in relation to the marketing of energy drinks.

Red Bull GmbH and Red Bull Australia Pty Ltd understand and share the concern that it is inappropriate for energy drinks to be marketed at younger children. RED BULL energy drink has not been, and will not be, marketed in such a manner.

Red Bull GmbH and Red Bull Australia Pty Ltd would be happy, subject to the Trade Practices Act 1974, to participate in an industry Code of Practice that seeks to ensure that energy drinks are not marketed to younger children. We would see an agreement not to place product in primary school canteens, and possibly an agreement to restrict container sizes, could be useful in achieving the desired outcome.

However, there are two concerns that apply generally to self-regulatory marketing Codes of Practice:

(a) in general terms, only responsible manufacturers agree to be bound by such Codes, while those who are the root cause of the problems are usually reluctant to agree to the Code and/or to submit to compliance measures; and

(b) such Codes in Australia contravene the prohibition in Part IV of the Trade Practices Act against understandings between competitors that lessen competition - this is not a fatal objection, as an authorisation from the ACCC can be obtained if the Code of Conduct is held to be in the public interest, but this can be a costly and time-consuming process.

In principle, however, we are willing to pursue the idea at least in the first instance.

Regards

Chris Preston
email: chris.preston@weekespreston.com.au

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**ATTACHMENT 5**

## EXECUTIVE SUMMARY OF THE EXPERT WORKING GROUP ON CAFFEINE, JUNE 2000.

The Australia New Zealand Food Authority (ANZFA) established an Expert Working Group (consisting of external experts) to examine the wider aspects of the safety of dietary sources of caffeine.

The task and terms of reference for the group were to examine the potential for acute toxicological/pharmacological effects at low doses of caffeine (Term of Reference A), the potential for addictive effects (Term of Reference B) and identification of any other caffeine-related hazards particularly in children (Term of Reference C).

The conclusions from the Expert Working Group are as follows:

### Term of Reference A

Several variables need to be considered when interpreting studies with caffeine. These include the pharmacokinetics (e.g. age and sex differences, pregnancy, liver disease, diet, smoking and concomitant drug therapy), the source of caffeine (e.g. caffeinated beverages such as coffee may have physiological effects related to other constituents), the study design, the population studied and the sample size.

It would be valuable to have data which would enable dose-response and plasma concentration-response curves to be established for different effects (end-points). However, it appears that the relationship between dose and physiological response is continuous down to the lowest levels studied (although these effects are increasingly subtle as dosage is reduced). A 'no effect' level has not been identified. It is likely that caffeine causes subtle effects at very low dose levels, although their detection is ultimately dependent on the sensitivity of indicators and tests employed.

Although larger controlled studies are required to confirm the dose-related effects of low-dose caffeine, the following conclusions can be drawn from the available data:

- There are reports of enhanced performance and mood effects at doses of 37.5mg (0.54 mg/kg bw/day in 70 kg adults);

- There are reports of increased anxiety levels in children at doses of 95mg (3 mg/kg bw/day in children aged 5-12 years with a mean bodyweight of 32kg) and at 210mg in adults (3 mg/kg bw/day in 70 kg adults; and

- Caffeine has been reported to reduce the ability to sleep at doses of 100mg (1.4 mg/kg bw/day in 70 kg adults) at bedtime.

In conclusion, in addressing term of reference A, the threshold dose for possible behavioural effects in children remains unclear and it is recognised that further studies are needed to elucidate the potential effects of caffeine in children at doses *that may* be ingested from dietary sources.

**Term of Reference B**

It is concluded that caffeine at doses typically consumed in the diet may lead to withdrawal effects and some physical dependence in adults. The prevalence of such effects has been variable, as has the interpretation and their intensity is minimal in most individuals. Further research will be required at doses typically consumed in the diet to examine whether similar withdrawal effects and physical dependency occurs in children.

**Term of Reference C**

It would appear that a precise link between caffeine contributing to cardiovascular disease has not been established. The published literature provides little evidence that caffeine in typical dosages consumed in the diet contributes to hypertensive disease.

If it is assumed that caffeine use in childhood lays the foundations for life-long use, there may be some grounds for concern that the consumption of caffeine-containing substances by children could be considered to be undesirable. At this stage it is not possible to conclude that patterns of caffeine consumption established early in life can contribute to negative long-term health outcomes in children and that effects observed in adults can be extrapolated to children.

**EXECUTIVE SUMMARY OF PROFESSOR JACK JAMES'S DISSENTING REPORT TO THE EXPERT WORKING GROUP ON CAFFEINE, JUNE 2000.**

Professor James's report is a commentary on the Final Report of the ANZFA Expert Working Group on Caffeine. Although a Member of the Working Group and a contributor throughout the protracted period of the Group's deliberations, Professor James declined co-authorship of the Final Report. His reasons for declining authorship arouse in a particular context, which he wished to explain. His report is in two parts: Part 1 comments on operational aspects of the Expert Working Group, and Part 2 comments on the content of the Working Group's Final Report. Given below is the executive summary from Professor James' report.

## THE SAFETY ASPECTS OF DIETARY CAFFEINE
### Executive Summary

This report is a commentary on the Final Report of the ANZFA Expert Working Group on Caffeine. Although a Member of the Working Group and a contributor throughout the protracted period of the Group's deliberations, the present author declined co- authorship of the Final Report for reasons of professional integrity. It is this author's opinion, based on extensive familiarity with the relevant scientific literature, that the contents of the Final Report are potentially harmful to the public interest. Accordingly, it is the intended that this commentary, which reflects the author's individual deliberations, be distributed as an essential supplement to the Final Report.

### Cardiovascular Health and Term of Reference C

The Final Report provides an inadequate and misleading account of current scientific knowledge concerning the effects of dietary caffeine on cardiovascular health. Conclusions contained in Section C2.0 Cardiovascular effects of caffeine indicate poor understanding of the experimental and epidemiological evidence on the cardiovascular effects of caffeine. It my be confidently concluded that any extension of the use of caffeine in soft drinks will create quantifiable harm to the long-term cardiovascular health of consumers, a large proportion of whom are likely to be children.

### Miscellaneous Comments and Terms of Reference A and B

- The Final Report is confused in relation to Term of Reference A. At one point, it is stated that there 'appears to be evidence of a "no effect" level', whereas mention is made later of 'the threshold dose'. If there is no identifiable level at which effects are absent, then there can be no threshold.

- Insufficient attention is given in the Final Report to the available evidence showing the harmful behavioural effects in adult and child caffeine consumers during brief periods of abstinence (caffeine-withdrawal effect).

- Caffeine-withdrawal syndrome is a well established phenomenon, the symptoms of which include headache, mood disturbance and fatigue.

- Regarding Term of Reference B, it is reasonable to speak of caffeine as 'addictive', because repeated use produces physical dependence.

- Contrary to the impression given in the Final Report, well-controlled studies continue to implicate maternal caffeine use as a cause of adverse pregnancy outcomes.

- Contrary to the impression given in the Final Report, there is every reason to believe that the harmful effects of dietary caffeine in adults extrapolate to children.

**Conclusions**

- Habitual use of caffeine leads to physical dependence (as evidenced by the existence of a well characterised abstinence-induced 'withdrawal syndrome').
- Habitual use has no demonstrated benefits.
- Dietary caffeine has harmful physical and behavioural effects.
- The harmful effects of caffeine probably extrapolate to children.

**ATTACHMENT 6**

# SAFETY ASSESSMENT REPORT

The safety assessment for the ingredients of energy drinks[1] considers nutritional and toxicological aspects of these substances. The nutrients, along with other added substances, are assessed on the basis of safety and generally recognised physiological function.

The maximum levels for each substance are based on the safety assessment and composition of the product that is the subject of the application. No judgment has been made as to the efficacy of these substances.

## Dietary Modelling

The consumption data for dietary modelling were based on that derived from national nutrition surveys in Australia (1995) and New Zealand (1997). Modelling scenarios for vitamin intakes were based on 'normal' consumption patterns, from the national nutrition surveys, plus the addition of 500 mL per day of energy drink. Data from the European Commission (1999) indicates 9% of the population could be described as 'regular consumers' of energy drinks with intake likely to be in the order of 500 mL per day (2 x 250 mL cans). The 500 mL daily intake figure has been used in this dietary modelling but applied to the whole population rather than adjusting for the 9% in order to assess worst case and individual consumer scenarios. Data included refer to the 18-34 year age group, the self reported target group of the energy drink companies.

The dietary modelling report is appended to this Safety Report.

## B Vitamins

Most energy drinks are characterised by the addition of a variety of B vitamins. Most commonly added to energy drinks are the vitamins ***thiamin, niacin, vitamin B6, vitamin B12, and pantothenic acid.*** Each of these are considered below in the context of Application A394 (Energy Drinks).

## Thiamin

*Role*

Thiamin is an essential coenzyme in the citric acid cycle, which has a pivotal role in the metabolism of fats, proteins and carbohydrates. The human body cannot store thiamin and thus there is rapid excretion of thiamin after large doses (5 mg/day). The maximum amount of oral thiamin absorption is estimated to be 5 – 10 mg /day (Institute of Medicine, 1998), after which the absorption declines and rapid excretion of thiamin occurs.

[1] 'Energy drinks' is the commonly used term for non-alcoholic water-based caffeinated beverages, formulated for the intended effect of energy enhancement. The term 'energy drinks' will be used for the purposes of this report.

*Adverse effects*

Consumption of thiamin as part of food or in supplements is not known to have a toxic effect even if consumed in large doses. In the US, no upper limits have been established for thiamin because there is no evidence of toxicity. Supplements of up to 50 mg/day are readily available without prescription.

*RDI*
The current Australian and New Zealand RDI for thiamin is 0.7-1.1 mg/day (Truswell 1990), based on 0.1mg thiamin/ 1000kJ.

*Other regulations*

The standard for Formulated Supplementary Sports Foods (Volume 1 of the *Food Standards Code*) permits an upper limit of 2.2 mg/day.

The US recommended daily allowance (RDA) for thiamin in adult men is 1.2 mg/day and in adult women is 1.1 mg/day. As there are no reports of adverse effects from consumption of excess thiamin and the data are inadequate for a quantitative risk assessment, the US have not set an upper limit (UL).

*Current Intakes*

Current dietary intakes in Australia are a median intake of 1.7 mg/day for women and 1.9 mg/day for men (Australian Bureau of Statistics 1998). In New Zealand the mean intakes are slightly lower at 1.2 mg/day for women and 1.7 mg/day for men (Ministry of Health 1999).

Preliminary market surveillance indicates that the current levels of thiamin added to formulated caffeinated beverages range from 0.3 – 3.2 mg/100 mL.

*Dietary Modelling*

Dietary modelling for thiamin amongst Australian and New Zealand consumers shows an intake of approximately 41 times (41 mg/day) the RDI with the 95$^{th}$ percentile yielding approximately 43 times (43 mg/day) the RDI.

*Conclusion*

As there is no evidence of toxicity from consumption of thiamin at high levels (up to 50 mg/day), a maximum limit of 20 mg/250 mL (80 mg/L) is proposed as a conservative limit that will accommodate known current market formulations of formulated caffeinated beverages.

**Niacin**

*Role*

Niacin is one of the B group vitamins and includes nicotinic acid and nicotinamide. Most of the vitamin is present in the body in the form of nicotinamide dinucleotide (NAD) and nicotinamide dinucleotide phosphate (NADP).

These coenzymes play a major role in reduction-oxidation reactions critical in glycolysis, fatty acid metabolism, tissue respiration and detoxification. Through the glycolytic pathway niacin is involved in the release of energy from carbohydrates. The action of niacin metabolites in cellular metabolism is so widespread that lack of niacin results in major damage to cell respiration and energy metabolism. There may be some functions of niacin associated with the action of insulin and with metabolism of glucose (Institute of Medicine 1998).

The body's niacin requirement is met by dietary nicotinic acid and nicotinamide as well as the conversion of tryptophan in dietary protein to nicotinamide (approximately 1 mg niacin produced for every 60 mg tryptophan). This conversion rate depends on a number of dietary and metabolic factors and can vary substantially in humans. Niacin in the form of nicotinic acid has been used therapeutically to treat hyperlipidemia and other disorders.

*Australian and New Zealand RDI*

The current Australian and New Zealand Recommended Dietary Intake (RDI) for niacin is 18 – 20 mg niacin equivalents per day allowing for some of the conversion of the amino acid tryptophan to niacin (Truswell 1990).

*Adverse effects*

There is no evidence of adverse effects from the consumption of the normal levels of niacin in foods. Adverse effects can be observed following high intakes of pre-formed niacin, which may be achieved through consumption of pharmacological preparations or supplemental dietary products.

Adverse effects have been observed with intakes of nicotinamide greater than 3000 mg/day compared with intakes of nicotinic acid of 1500 mg/day. Intakes of 3 – 9 grams/day have been associated with liver dysfunction and ultimately liver damage. Large doses of nicotinic acid (3 grams/day) have been used to treat people with hypercholesterolaemia and other disorders. These levels have produced glucose intolerance in otherwise healthy individuals during both short and long term intakes of nicotinic acid (Institute of Medicine, 1998). Ocular effects (blurred vision, toxic amblyopia, macular oedema and cystic maculopathy) were observed at niacin doses of and greater than 1500 mg/day.

The United States (US) set a tolerable upper intake (UL) (the highest level of daily nutrient intake that is likely to pose no risks of adverse health effects to almost all individuals in the general population) of unsupervised intake of 35 mg /day based on the levels that may result in 'niacin flushing' (an effect associated with extreme capillary dilation). The effect includes a burning, tingling and itching sensation as well as a reddened flush primarily on the face, arms and chest. Flushing is associated with a continuous rise in plasma nicotinic acid concentrations and occurs in patients treated with nicotinic acid therapeutically. Nicotinamide does not appear to be associated with flushing. However, the UL for nicotinic acid based on flushing is considered a protective measure against potential adverse effects of nicotinamide.

Levels well in excess of 35 mg/day, however, have been used under medical supervision to achieve enhanced functions with no long term detrimental effects to the consumer (Institute of Medicine, 1998).

*NZ Dietary Supplement Regulations*

The New Zealand *Dietary Supplement Regulations 1985* currently permit the addition of niacin to dietary supplements at a maximum daily dose of 100 mg /day.

*Current Intake*

The mean dietary intake of niacin in New Zealand is 36 mg NE/day with the 90$^{th}$ percentile intake at 52 mg NE/day (Ministry of Health, 1999). It is reasonable to assume that these figures almost totally reflect the natural food sources of niacin and the body's conversion of tryptophan to niacin, as the survey collection was predominantly carried out prior to fortification of foods with niacin. The mean niacin intake in Australia is 50.7 mg NE/day (Australian Bureau of Statistics, 1998). As noted above, no adverse effects have been identified with natural levels of niacin in foods or from the conversion of tryptophan in dietary protein to niacin.

*Dietary modelling*

Dietary modelling data for Australia and New Zealand indicates that 'regular consumers' of formulated caffeinated beverages would achieve an intake of approximately 4 times (80 mg/day) the RDI for niacin equivalents with the 95$^{th}$ percentile being approximately 6 times (120 mg/day) however, these levels are reduced considerably once modelling is adjusted for pre-formed (i.e. fortificant) niacin only (see Appendix to this report).

The level of niacin in *Red Bull* is declared as 20.0 mg/250 mL serve. Based on the European experience of consumers of formulated caffeinated beverages averaging 1 – 2 cans per day an additional intake of 20 - 40 mg niacin/day would be consumed by regular consumers of *Red Bull*.

*Discussion*

As noted above, even though higher levels have been used for therapeutic purposes, and higher intakes have been noted with no adverse effects, the US UL for niacin is set at 35 mg (pre-formed niacin)/day on the basis of 'flushing' effects (this level includes a safety factor of 1.5). The lowest observed effect level is 50 mg (Institute of Medicine, 1998). It should be noted that some individuals are more susceptible to 'flushing' than others, particularly those with certain disorders such as liver disease, diabetes mellitus, migraine headaches, gout, inflammatory bowel disease, alcoholism, peptic ulcer disease and cardiac arrthymias (Institute of Medicine, 1998). This list of disorders covers a number of sub-groups within the population and as such, it is considered that it would be appropriate to advise consumers generally to limit intakes of food products containing supplemental niacin such that the above limit is not exceeded.

Given that the bioavailability of niacin can vary enormously within humans due to differences in the conversion of tryptophan to niacin, and that niacin as added to FCBs is predominantly in the form of nicotinamide rather than nicotinic acid, there is scope to set the upper limit to 40 mg niacin per day, whilst still maintaining a cautious approach.

*Conclusion*

This assessment concludes that consumers should be advised not to consume more than 40 mg niacin /day from formulated caffeinated beverages (i.e. no more than 2 cans of beverage containing 20 mg/250 mL serve, or 80 mg/L of FCB).

**Pantothenic Acid**

Pantothenic acid, another of the B group vitamins, is a part of the coenzyme A molecule, which plays an essential role in the catabolism of macronutrients. Pantothenic acid is widely distributed in all animal and plant tissues. There is no convincing evidence of pantothenic acid deficiency in humans.

The US has established Dietary Reference Intakes (DRI) of pantothenic acid of 5.0 mg/day. No tolerable upper intake level (UL) has been established, as there are no reports of adverse effects from oral pantothenic acid (Institute of Medicine, 1998).

Current intakes of pantothenic acid in New Zealand indicate a mean intake of 4.7 mg/day (LINZ, 1991). There are currently no Australian intake data available on pantothenic acid.

*Dietary Modelling*

Dietary modelling scenarios did not include pantothenic acid, as this vitamin was not included amongst the consumption data in the relevant national nutrition surveys. The current level of pantothenic acid in *Red Bull* is 5.0 mg/ 250 mL serve.

*Discussion and conclusion*

In the absence of reported adverse effects or an established UL it is appropriate to consider any other information available such as, history of use. The European experience of regular consumption of 500 mL *Red Bull* / day indicates that intakes of pantothenic acid at a regular consumption of 10 mg/day are most probably safe. Therefore, it is proposed that this level be advised as the maximum daily consumption of pantothenic acid from energy drinks.

**Vitamin B6**

Vitamin B6 functions as a coenzyme in the metabolism of amino acids and glycogen.

The current Australian and New Zealand RDI for vitamin B6 ranges from 0.9 – 1.9 mg/day (with a recommendation that upper levels should be no more than 10 mg/day on a regular basis in normal individuals (Truswell et al, 1990)). These levels are notably lower than the US UL of 100 mg/day as discussed below.

The latest recommendations from the US have set a recommended daily allowance (RDA) for adult men and women at 1.3 mg/day.

There have been no reports identified associating adverse effects with high intakes of vitamin B6 from food sources. In the US, a tolerable upper level (UL) was established based on the endpoint of sensory neuropathy. The UL is set at 100 mg/day (Institute of Medicine, 1998).

The current mean intake of vitamin B6 in New Zealand is 1.5 mg/day with the 90$^{th}$ percentile having intakes of 2.1 mg/day (Ministry of Health, 1999). There are no Australian intake data for vitamin B6.

Dietary modelling of the potential intakes of vitamin B6 from a fortified food supply among the New Zealand population show the highest potential intakes are among young males with the 90$^{th}$ percentile intake being 6.3 mg/day. This is a worst-case scenario (Wilson et al, 1994). The current level of vitamin B6 in *Red Bull* is 5.0 mg/250 mL serve.

*Dietary Modelling*

Dietary modelling data indicate intake of vitamin B6 would approximate 7.7 times (11.5 mg/day) the RDI or 8.8 times (13.2 mg/day) the RDI for the 95$^{th}$ percentile on the basis of 500 mL *Red Bull* per day (see Appendix to this report).

*Discussion*

On the basis of the above, dietary intakes (including *Red Bull*) of vitamin B6 are well below the US UL of 100 mg. This level has however, been the topic of debate (Warden, 1998; Editorial BMJ, 1998) and there has been considerable public interest in the UK regarding ready availability of relatively high amounts of vitamin B6 (50 – 250 mg) in dietary supplements (Joint Food Survey and Standards Group, 1997).

This discussion focused on the appropriateness or otherwise of such levels in foods (or food supplements) and noted the [UK] government's recommendations that doses over 10 mg/day of vitamin B6 were medicinal. The Department of Health's committee on toxicity were persuaded that some individuals would develop adverse symptoms from prolonged intakes of average supplemental doses (117 mg/day) of vitamin B6 and that, in the absence of potential benefits of higher doses, a restrictive position should be taken. However, the Agriculture Select Committee, which monitors food safety, recommended that the government should permit a voluntary limit of 100 mg/day largely based on the US determination that 500 mg/day was the level of lowest observed adverse effect (Warden,1998).
The Agriculture Select Committee has recommended that supplements containing vitamin B6 should display a warning that daily intakes above 100mg may carry health risks.

Generally, it is considered that active substances in foods or medicines also take into account the least amount required to achieve the purpose. In the case of energy drinks, amounts required for purpose or associated benefits have not been clearly established (except for the defining ingredients) and therefore do not serve to provide upper limits.

*Conclusion*

Allowing large amounts of nutritive substances in generally consumed foods represents a new paradigm in the regulation of foods in Australia and as such, ANZFA considers a cautionary approach to be appropriate. In the case of vitamin B6 there is a large discrepancy between usual dietary intakes, history of use from energy drinks and the US UL. Therefore, it is proposed that advice to consumers be conservative and based on history of use, rather than the US UL. This represents 10 mg vitamin B6 from energy drinks/day.

**Vitamin B12**

Vitamin B12 functions as a coenzyme in protein metabolism for a critical methyl transfer reaction that converts homocysteine to methionine. Vitamin B12 also has a role to play in the maintenance of myelin in the nervous system. The body has good storage capabilities for vitamin B12 and also uses it efficiently such that requirements are small and symptoms of deficiency slow to appear.

The current Australian and New Zealand RDI for vitamin B12 is 2 mcg/day. There does not appear to be a concern with adverse health effects of vitamin B12 at up to levels of 20 times the recommended intakes (Truswell, 1990).

The current mean New Zealand intake of vitamin B12 is 4.9 mcg/day with the 90$^{th}$ percentile of the population averaging intakes of 8.2 mcg/day (Ministry of Health, 1999). There are no Australian national intake data for vitamin B12.

The current level of vitamin B12 in *Red Bull* is 5 mcg/250 mL serve. The average consumption of 1-2 cans per day (European Commission, 1999) would provide an additional 5 –10 mcg vitamin B12 from energy drinks.

The New Zealand Dietary Supplement Regulations set a maximum daily dose for vitamin B12 of 50 mcg/day although this is currently being reviewed.

*Dietary Modelling*

Vitamin B12 was not included in the Australian National Nutrition Survey however, the dietary modelling scenario for New Zealand data showed that intake of vitamin B12 would approximate 7 times (14 mcg) the RDI and 10 times (20 mcg) the RDI for the 95$^{th}$ percentile.

*Discussion and conclusion*

In the absence of any other defining data, history of use has been taken into account and it is proposed that maximum intakes of vitamin B12 from energy drinks be set at 10 mcg/day.

**Riboflavin**

Riboflavin is involved with a number of enzyme systems concerned with hydrogen transfer and as such is a constituent of all metabolising cells. There is limited storage of riboflavin in the body. Large doses of riboflavin produce no known pharmacological effects and the toxicity of the vitamin is considered to be extremely low due in part to ready excretion of excess amounts. The US has not set an upper level due to lack of evidence of toxicity data (Institute of Medicine, 1998).

Recommended intakes are made on the basis of energy intakes with the RDI for adult males being 1.7 mg/day.

Current median dietary intakes in Australia are 2.0 mg/day for females and 2.3 mg/day for males (Australian Bureau of Statistics, 1998). In New Zealand the mean dietary intakes are 1.6 mg/day for females and 2.1 mg/day for males (Ministry of Health, 1999). In the US the 95$^{th}$ percentile intake from both food and supplements ranges from 4 – 10 mg/day.

Riboflavin is not commonly added to energy drinks as a nutritive substance rather, it is generally added for its technological function as a colouring agent.

*Dietary Modelling*

Consumption data on riboflavin, for Australian and New Zealand consumers, used in dietary modelling, produced an approximated intake of 11 times (22 mg/day) the RDI or 12 times (24 mg/day) the RDI when expressed as the 95$^{th}$ percentile (see Appendix to this report).

*Conclusion*

It is proposed that, in accordance with the composition of *Red Bull* and knowledge of regular consumption of 500 mL per day, the advised consumption limit for riboflavin from energy drinks be set at 20 mg/day.

***Amino Acids***

**Taurine**

Taurine is an amino acid naturally present in the diet. It is a metabolic product of sulphur amino acids, mainly biosynthesised from methionine and cysteine metabolism. The role of taurine in a number of body processes is not clearly understood although there appears to be a role in membrane stabilisation, bile salt formation, antioxidation, calcium homeostasis, growth modulation and osmoregulation (Redmond et al, 1998).

Taurine is found in meat, seafood and milk. A daily intake in humans has been estimated between 40 – 400 mg (Hayes and Trautwein, 1994). Taurine levels in energy drinks range up to 4000 mg/litre (the current declared level in *Red Bull*).

The intake of taurine from regular consumption of some taurine–containing energy drinks is several times higher than that from the rest of the diet.

The available toxicological studies on taurine are summarised below:

**Summary of available toxicity studies**

Adverse effects shown in italics.
NOEL – no observed effect level.

| Study | Dose | Route of exposure | Toxicological endpoint/NOEL |
|---|---|---|---|
| **Human studies**<br><br>*KendlerBS (1989) Yamori Y et al, 1996)* | 3000 or 6 000 mg/day in patients with mild hypertension (43 or 86 mg/kg bw/day in 70 kg adults) for **6 weeks**. | Oral | Decreased blood pressure in hypertensive patients.<br><br>No evidence of adverse effects. |
| *Franconi F (1995) et al* | 1500 mg/day for **90 days** in adults with and without insulin-dependent diabetes (21mg/kg bw/day ) | Oral | No evidence of adverse effects |
| *Mantovani J and DeVivo DC (1979)* | **Single** doses taurine 375 to 8000mg/day (16-150 mg/kg bw) in epileptic patients | Oral | No evidence of adverse clinical or metabolic effects. |
| **Animal studies**<br>Acute studies<br><br>*Kihara K et al (1991)*<br><br>Rats | Single doses of 5g/kg bw administered to rats via gavage | Oral | No deaths or adverse effects observed for 14 days) |
| Subchronic studies | | | |
| *Cantafora A et al (1994)*<br>• 2-week study in rats | 1% taurine in drinking water (2600 mg/kg bw/day) | Oral | Changes in neutral lipids, phospholipids and enzyme activities related to lipid metabolism in liver.<br><br>No NOEL established |
| *Ordaz-Tellez MG and Ramos-Morales P (1997)*<br>• 2-week study in Guinea Pigs | 0.4% (4000 ppm) in drinking water (462 mg/kg bw/day | Oral | Fatty infiltration in liver<br><br>No NOEL established |
| *Furukawa S et al (1991)*<br>• 13-week | 0, 500, 1000 and 2000 mg/kg bw/day. Taurine administered **IV.** | IV | Increased water consumption at 1000 and 2000 mg/kg bw/day. Haemosiderin |

| | | | |
|---|---|---|---|
| study in rats. | | | deposition in lungs at highest dose.<br><br>NOEL 1000mg/kg bw/day due to minor effects on water consumption. |
| **Developmental toxicity** | | | |
| Takahaski et al (1972) | 0 or 4000mg/kg bw/day in mice on day 7 to 14 of gestation | *Oral (Gavage)* | No deaths or adverse developmental effects observed post treatment. |

The available animal and human studies indicate that taurine is of low toxicity. No adverse effects were observed following single dose administration in rats up to 5g/kg bw or in humans up to 150 mg/kg bw. Long-term studies in rats showed that taurine up to a dose of 1000mg/kg bw/day had no adverse effects for a period of 13 weeks.

Long-term studies in humans revealed no adverse effects when taurine was administered orally at doses of 3000 or 6000 mg/day (equivalent to 43 or 86 mg/kg bw/day) for a duration of 6 weeks or at doses of 1500 mg/day (21mg/kg bw/day) for a duration of 90 days.

*Estimated intakes in humans*

A daily intake in humans from the normal diet has been estimated at 40-400 mg/day (European Commission, 1999). Taurine levels in Red Bull can be up to a maximum of 4000mg/litre.

The European Commission Report considered that 500mL was a reasonable estimate of mean intake of energy drinks. Based on this, consumers could have an intake of 2000 mg/day (1000mg/250mL), i.e. 29mg/kgbw/day in 70kg adults. This represents a 5-fold increase compared to maximum level from normal diet (400mg) or 50-fold increase compared to minimum dietary levels (40mg).

**Conclusion**

The available data indicates that taurine is a naturally present amino acid in the diet, is readily absorbed, widely distributed in the body and is a normal metabolite of humans. Although the precise role of taurine in humans is still being elucidated, the available toxicological and clinical studies indicate that it is of low toxicity even at high doses. It is known that regular consumers of energy drinks consume up to 2000mg/day from energy drinks with no apparent reports of adverse effects.

The above information indicates that consumption of 2000mg/day of taurine from energy drinks can be assumed to be safe and may be advised as such.

**Other Ingredients**

Glucuronolactone

*Absorption, Metabolism and Excretion*
Glucuronolactone is the gamma-lactone of glucuronic acid and is a normal human metabolite formed from glucose. It is biosynthesised from glucose in humans with glucuronic acid its precursor. Glucuronolactone is rapidly absorbed and metabolised when administered orally via the following pathways:

- glucuronate oxidation to glucaric acid (a C6-dicarboxylic acid) and excretion in the urine (measurable levels in the urine 1h post ingestion, peaking at 5h);

- metabolism to L-xylulose and xylitol and excretion in the urine or further metabolism via the pentose cycle; and

- formation of L-gulonolactone which in most mammals (except primates including humans or guinea pigs) may then be metabolised to L-ascorbic acid. In rats, it has been shown that there is additional oxidation to ascorbic acid, however, humans and guinea pigs lack the specific enzyme for conversion to ascorbic acid. Therefore, it has been suggested that rats may be an inappropriate model in order to elucidate the effects of glucuronolactone via oral administration.

In summary, glucuronolactone is an intermediate in the metabolic pathways in humans. Following oral ingestion glucuronolactone is rapidly metabolised and excreted in the urine as glucaric acid, xylulose or xylitol. These latter compounds pose no toxicological concerns.

*Toxicological studies*

Glucuronolactone is therefore considered to be of low acute toxicity. It has been used in long term therapy of chronic carriers of the typhoid organism because of its ability to inhibit viral and antibacterial beta- glucuronidase. Administration of between one and a few grams per day did not give rise to problems (European Commission, 1999).

The available toxicological studies on glucuronolactone are summarised in the table below:

**Summary of available toxicity studies**

| **Study*** | **Dose** | **Route of exposure** | **Toxicological endpoint/NOEL** |
|---|---|---|---|
| *Animal studies* | | | |
| **Acute Studies**<br><br>Register of Toxic effects of Chemicals | 10,700 mg/kg bw glucuronolactone administered orally in *rats.* (Not specified as to whether administered in diet, drinking water or by gavage) | Oral | No adverse effects observed |
| *Kuzuya et al (1973)* | IV administration at 400 mg/kg bw in dogs | IV | Slight increase in plasma insulin and glucose concentrations. |
| **Chronic long-term studies**<br><br>*Ahrens et al (1987)* | 275 mg/kg bw/day in rats in drinking water for duration of life | Oral | No adverse effects observed |
| *Di Filippo and Blumenthal (1972))* | 0, 1.9, 3.8 or 5.7g/kg bw/day in hamsters in drinking water for 28 days | Oral | No adverse effects observed |
| *Human studies* | | | |
| **Humans-endurance athletes**<br><br>*Geiss et al (1994)* | Single doses of a drink containing 1.2g glucuronolactone, 2g taurine, 160 mg caffeine, 105g glucose, 43g sucrose administered to adult athletes (equivalent to 15 mg/kg bw glucuronolactone) | Oral | No adverse effects observed |

The toxicological studies available are limited, particularly in relation to long-term effects. There is a reasonable amount of data from animal and human studies which indicates that glucuronolactone has low acute toxicity. No adverse effects were observed following single dose administration in rats up to 10 g/kg bw or following long-term exposure up to 275

mg/kg bw for lifetime exposure. In humans, glucuronolactone is without harmful effects following a single dose level of 17 mg/kg bw.

**Estimated intakes in humans**

Daily intake of glucuronolactone in humans from normal dietary sources has been estimated at an average level of 1.2-2.3 mg/day (European Commission, 1999).

The European Commission Scientific Committee for Food Report considered that 500 mL/day was a reasonable estimate of mean intakes of energy drinks. Based on this, consumers could have an intake of 1200 mg/day (600 mg/250 mL), i.e.. 17 mg/kgbw/day in 70 kg adults (500-fold increase compared to maximum level from normal diet). While there are no data available on the intake of these drinks in Australia, 500 mL/day is considered to be a reasonable estimate.

**Conclusion**

The available data indicate that glucuronolactone is a naturally occurring endogenous metabolite in the body that is rapidly metabolised to innocuous metabolites, glucaric acid, xylitol and xylulose, all of which are excreted in the urine.

From the data available, it is unlikely that the capacity of these metabolic pathways would be exceeded by high doses of glucuronolactone or that glucuronolactone itself would be associated with any adverse effects in humans. However, these data are limited and the levels of glucuronolactone in *Red Bull* are far greater than those found in the normal diet.

It is considered that the upper level of intake of glucuronolactone should be limited to 1200 mg/day, which is equivalent to known regular consumption of 500 mL of *Red Bull* energy drink.

**Inositol**

Myo-inositol, the nutritionally active form of inositol, is a constituent of the phospholipid phosphatidylinositol. Inositol (myo-inositol) is a six carbon, cyclic sugar-related alcohol that is abundant in mammalian tissues. Inositol plays a key role as cellular mediators in signal transduction, growth and metabolism regulation.

Serum inositol levels and the inositol pool in humans are tightly regulated primarily by renal metabolism and clearance mechanisms. Some human tissues have the ability to synthesize inositol from D-glucose.

Foods of both plant and animal origin are rich in free and phosphorylated inositol. In foods of animal origin, inositol is available as both the free and phosphorylated form and as inositol phospholipid, whereas the predominant form of inositol in plants exists as phytate, which is known to limit the availability of many essential nutrients.

Because of its endogenous synthetic capabilities, inositol has not been listed as an essential nutrient in the recommended intakes or the recent dietary reference intakes for humans in the United States.

Although clear-cut deficiency states of myo-inositol have not been identified in humans, they have been described in other animals. Several claims have been made for myo-inositol including lowering blood concentrations of triglycerides and cholesterol and generally protecting against cardiovascular disease in humans.

Some people take 1 – 2 grams of myo-inositol either to help them sleep or to relieve anxiety. There are no scientific studies to support this.

Dietary supplements of myo-inositol have been successful in preventing the development of neuropathy in diabetic rats.

Adult Americans consume about 500 mg - 1 gram of myo-inositol per day mainly in the phospholipid form and as phytic acid present in plant sources. Foods richest in myo-inositol are fruits, nuts, beans and grains.

Studies have been undertaken on small groups of humans who consumed 20g /day of myo-inositol for a period of 14 days without any adverse effects (Arendrup et al, 1989).

Other studies undertaken on a larger group of diabetics who consumed 6 grams of myo-inositol for two months showed no adverse effects.

The level of inositol in *Red Bull* is 50 mg/250 mL serve. The recommended intake of 5 cans/day would provide an additional 250 mg of inositol per day. From the available data this does not appear to be a level that would cause any adverse effects and consumption by regular users in Europe indicates safety at up to 100mg inositol/day.

**Caffeine**

*Current Consumption*

The caffeine intakes of New Zealand adults - from tea, coffee and soft drinks -has been estimated from the National Nutrition Survey (1997). No data were collected on energy drinks as these products were not established on the New Zealand market at the time of data collection. The mean per capita daily caffeine consumption is 175 mg. This equates to 2.7 mg/kg bw/day. Coffee contributes most of the caffeine at 49%, tea at 46% and soft drinks at 5%.

Data from the 1995 National Nutrition Survey in Australia indicates that overall caffeine consumption in Australia for adults consuming caffeine containing products is 3 mg/kg bw/day. For adults 62 % of the caffeine is from coffee, 31.2 % is from tea and 5.2 % is from soft drinks.

There are no data on current consumption of energy drinks in either Australia or New Zealand. The recent report by the European Commission (1999) estimated that only 9 % of the population were regular users of energy drinks. Caffeine intake from energy drinks for regular users was estimated at 160 mg/day or 2.5 mg of caffeine/kg bw/day.

*Caffeine Intake from Energy Drinks*

Energy drinks typically have caffeine levels of 240 – 320 mg/litre.

Consumer research undertaken by Frucor, producers of the energy drink "V", suggest that energy drinks generally replace products such as coffee, tea and colas as 'pick-me-ups'. This position of energy drinks replacing other caffeine containing drinks is similar to the position in Europe (European Commission, 1999).

There are no data on caffeine consumption in children in New Zealand. Data from the 1995 National Nutrition Survey in Australia showed total caffeine consumption among 5 –12 year olds as 16.6 mg/day and among 13 – 19 year olds as 62.8 mg/day. There are limited data on consumption of energy drinks by children in either Australia or New Zealand. The main energy drink manufacturers, including the applicant *Red Bull*, maintain that their energy drinks are not marketed at children but targeted at young adults (18 – 34 years).

A survey undertaken by AC Nielson on consumption of energy drinks by New Zealand 10 – 12 year olds shows that only 2 % of children (10 – 14 years) consume energy drinks on a daily basis. This needs to be compared with 7 % of 10 – 14 year olds who drink coffee, 16 % who drink tea and 13 % who drink Cola on a daily basis.

## Guarana

Caffeine is the major xanthine present in guarana, together with small amounts of threobromine and theophylline. The caffeine content of guarana has been found to be as much as 5 percent w/w. The stimulant effects of guarana are most probably due to its caffeine content. A 1gram dose of guarana will contain as much caffeine as a medium strength cup of tea or instant coffee (Houghton, 1995).

The Therapeutic Goods Administration in Australia has recently imposed two conditions in relation to the use of guarana.

- The presence of caffeine in goods must be declared; and
- The quantity of caffeine per dosage unit must be declared.

ANZFA has proposed in the joint *Food Standards Code* that any food containing guarana must declare it as a source of caffeine.

*Further information*
Further information on caffeine is found at Attachment 5 (executive summary of the report from the Expert Working Group on Caffeine)

*Conclusion*
In accordance with these considerations, and those in Attachment 5, it is proposed that the maximum permitted level of caffeine (from any source) in energy drinks be set at 320 mg/litre.

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**Appendix 1 to Safety Assessment Report**

## Dietary Exposure Assessment Report

This report provides details of the estimated dietary exposure of several population subgroups to the substances found in *Red Bull energy drink.*

### Consumption Data

The 1995 Australian National Nutrition Survey (NNS) and the 1997 New Zealand National Nutrition Survey (NZNNS), surveyed 13 858 respondents aged over 2 years, and 4 636 respondents aged over 15 years respectively. These surveys used a 24-hour recall method to ascertain consumption patterns. Unfortunately, the data contains inadequate information on consumption patterns of energy drinks[1] due to their relatively recent emergence onto the market.

Current data on the consumption of energy drinks in Australia and New Zealand is limited. One Australian survey[2] assessed the incidence of consumption within a two-week period in 1999 however, this study did not record quantities consumed or frequency of consumption. The results from this survey are given in Table 1.

Table 1: Consumption of Energy Drinks in Australia in a Two Week Period during 1999

| Sample Number | % Consumers |
|---|---|
| 141 | 27% males aged 8-12 years |
| | 12% females aged 8-12 years |
| 240 | 24% males aged 12- 18 years |
| | 20% females aged 12- 18 years |

New Zealand data are available from the Panorama survey of 12 000 respondents aged 10 years and over, by AC Nielson in 1999. Two hundred and sixty four individuals aged 10 to 14 years were interviewed in relation to their consumption of energy drinks, and the resultant data are presented in Table 2.

Table 2: Energy drink consumption in New Zealand by 10 to 14 year olds

| Consumption rate | No. consumers | Percentage 10-14 year olds |
|---|---|---|
| At least once per day | 6 | 2 |
| Once a week | 21 | 8 |
| At least once a month | 37 | 14 |

### Proposed Energy Drink Composition

Based on a safety assessment and consideration of the applicants' requirements, the proposed maximum permissible levels (based on recommended daily consumption of 500 mL) of nutritive substances in energy drinks are as follows (note: a serve = 250 mL):

[1] 'Energy drinks' is the commonly used term for non-alcoholic water-based caffeinated beverages, formulated for the intended effect of energy enhancement. The term 'energy drinks' will be used for the purposes of this report.

[2] O'Dea & Rawstone, 2000 Letter to the Editor. Medical Journal of Australia 173:389

- Niacin* 70 mg/L
- Riboflavin 40 mg/L
- Vitamin B6 20 mg/L
- Vitamin B12 20 µg/L
- Pantothenic acid 20 mg/L
- Taurine 4,000 mg/L
- Glucuronolactone 2,400 mg/L
- Inositol 200 mg/L
- Caffeine 320 mg/L

(Including guarana and other caffeine sources)

* The modelling for niacin was done according to the current composition of *Red Bull*, (i.e. 80 mg/L) the results of which indicated consumption in excess of safe levels (as determined by the safety assessment) for mean intakes of all age groups. Subsequently, the proposed consumption limits for niacin from Red Bull have been reduced to the compositional equivalent of 70 mg/L.

**Exposure Estimate**

Data from Europe (European Commission, 1999) indicates that the average consumption by 15 to 29 year olds of a particular energy drink (*Red Bull*) is approximately four cans per month. About 9% of the population have been estimated to be regular consumers of energy drinks with an average consumption of 500 mL per day (2 x 250 mL cans).

An exposure assessment was conducted using the proposed maximum permissible levels of nutritive substances (except for niacin*), listed above, for an intake of 500 mL of energy drink per day. This amount was assumed from the European experience. The contribution of nutritive substances from such an intake of energy drinks was summed with the intakes of those same substances, where available, from all respondents recorded in the national surveys using ANZFA's dietary modelling computer program, DIAMOND.

The industry-reported target population for energy drinks is 18 to 35 year olds, however, it is unrealistic to assume that other people outside this age range would not consume the energy drinks. Therefore, exposure estimates were conducted on a number of age groups, as outlined in Table 3.

Table 3: Age groups for scenario modelling using national surveys

| | **Australia** | **New Zealand** |
|---|---|---|
| Children | 5-12 years | |
| Teenagers | 13-17 years | 15-17 years |
| Adult target market | 18-34 years | 18-34 years |
| Other adults | 35+ years | 35+ years |

**Nutrient Modelling**

Nutrient intake data for the survey populations were derived using available Australian food composition data (for riboflavin, pre-formed fortificant niacin) and New Zealand data (for riboflavin, pre-formed fortificant niacin, vitamin B6, vitamin B12) according to DIAMOND's nutrient model.

The mean daily intake of nutrients can be determined, via dietary modelling, to assess consumption in relation to Recommended Dietary Intakes (RDIs). To assess the likely impact on nutrient intake from the consumption of energy drinks, a dietary modelling scenario was created to estimate total nutrient intake from the normal diet plus an additional 500 mL of energy drink per day. Therefore:

*Scenario A = 'normal' nutrient consumption + nutrient intake from 500 mL energy drink*

The niacin intake estimates were determined differently from other modelled nutrients. The niacin models were constructed on the assumption that all foods permitted to contain added (fortificant) niacin, as prescribed in the Australian *Food Standards Code* (Standards A9 - Vitamins and Minerals, R9 – Supplementary Foods and R10 – Formulated supplementary sports foods), did so, but at the levels for niacin equivalents (Australia) or pre-formed niacin (New Zealand) given in the food composition database (mostly lower than fortification levels). All niacin equivalents (Australia) or pre-formed niacin (New Zealand) in these foods was assumed to be from fortification.

The foods modelled include biscuits, bread (including in sandwiches and burgers), breakfast cereals, flour (all types), pasta, meat/yeast extracts, formula dietary foods, textured vegetable protein (TVP), supplementary drinks and drink bases, and sports foods. Products made from flour such as cakes were not included.

All other foods and beverages not permitted to be fortified with niacin were assigned a zero niacin concentration in the model. This excluded the natural niacin contributed by these foods, but since the reference value referred only to fortificant and supplemental niacin, this assumption was appropriate.

The additional nutrients/functional substances proposed to be incorporated into energy drinks (Pantothenic acid, Taurine, Glucuronolactone, Inositol) were not modelled because they were not included in the Australian or New Zealand Survey reports, therefore no data on were available as a benchmark without energy drinks.

Results

The Australian and New Zealand populations were divided into age groups as outlined above in Table 3. Table 4 shows the demographic characteristics of the respondents for the specified age groups for the Australian and New Zealand models.

Table 4: Demographic data from the Australian and New Zealand NNSs

| Australian data | | New Zealand data | |
|---|---|---|---|
| **Age Group.** | **No Respondents** | **Age Group.** | **No Respondents** |
| 5-12 yrs | 1 496 | | |
| 13-17 yrs | 793 | 15-17 yrs | 187 |
| 18-34 yrs | 3 547 | 18-34 yrs | 1 384 |
| 35+ yrs | 7 439 | 35+ yrs | 3 065 |

Tables 5 to 11 below show the modelling results for the Australia and New Zealand populations. Included in each table is the mean and 95$^{th}$ percentile nutrient intake from the national surveys as well as nutrient intake according to scenario A. The figures are also expressed as a percentage of RDI. The RDI values are derived from DIAMOND, and are based on nationally recognised NHMRC standards.

Table 5: Australian nutrient intakes, 5-12 years

| **Nutrient** | **Mean without energy drinks** | **Mean with energy drinks** | **95$^{th}$ percentile without energy drinks** | **95$^{th}$ percentile with energy drinks** |
|---|---|---|---|---|
| | **National survey** | **Scenario A** | **National survey** | **Scenario A** |
| Riboflavin (mg) | 2.2 | 22.2 | 4.7 | 24.7 |
| [Multiple RDI] | [1.71] | [14.8] | [3.7] | [16.5] |
| Niacin, assumed preformed (mg) | 10.6 | 50.6 | 24.6 | 64.6 |

Table 6: Australian nutrient intakes, 13-17 years

| **Nutrient** | **Mean without energy drinks** | **Mean with energy drinks** | **95$^{th}$ percentile without energy drinks** | **95$^{th}$ percentile with energy drinks** |
|---|---|---|---|---|
| | **National survey** | **Scenario A** | **National survey** | **Scenario A** |
| Riboflavin (mg) | 2.5 | 22.5 | 5.9 | 25.9 |
| [multiple RDI] | [1.5] | [11.3] | [3.3] | [13] |
| Niacin, assumed preformed (mg) | 12.5 | 52.5 | 34.7 | 74.7 |

Table 7: New Zealand nutrient intakes, 15-17 years

| **Nutrient** | **Mean without energy drinks** | **Mean with energy drinks** | **95$^{th}$ percentile without energy drinks** | **95$^{th}$ percentile with energy drinks** |
|---|---|---|---|---|
| | **National survey** | **Scenario A** | **National survey** | **Scenario A** |
| Riboflavin (mg) | 1.8 | 21.8 | 4.0 | 24.0 |
| [multiple RDI] | [1.07] | [10.9] | [2.37] | [12] |
| Niacin, preformed (mg) | 8.3 | 48.3 | 22.4 | 62.4 |
| Vitamin B6 (mg) | 1.4 | 11.4 | 2.9 | 12.9 |
| [multiple RDI] | [0.9] | [7.6] | [1.8] | [8.6] |
| Vitamin B12 (µg) | 4.0 | 14.0 | 10.2 | 20.2 |
| [multiple RDI] | [2.0] | [7] | [5.1] | [10.1] |

Table 8: Australian nutrient intakes, 18-34 years

| Nutrient | Mean without energy drinks | Mean with energy drinks | 95th percentile without energy drinks | 95th percentile with energy drinks |
|---|---|---|---|---|
| | National survey | Scenario A | National survey | Scenario A |
| Riboflavin (mg) | 2.3 | 22.3 | 5.1 | 25.1 |
| [multiple RDI] | [1.6] | [11.1] | [3.4] | [12.6] |
| Niacin, assumed preformed (mg) | 10.9 | 50.9 | 30.0 | 70.0 |

Table 9: New Zealand nutrient intakes, 18-34 years

| Nutrient | Mean without energy drinks | Mean with energy drinks | 95th percentile without energy drinks | 95th percentile with energy drinks |
|---|---|---|---|---|
| | National survey | Scenario A | National survey | Scenario A |
| Riboflavin (mg) | 1.9 | 21.9 | 3.8 | 23.8 |
| [multiple RDI] | [1.36] | [10.9] | [2.64] | [11.9] |
| Niacin, preformed (mg) | 8.1 | 48.1 | 21.1 | 61.1 |
| Vitamin B6 (mg) | 1.5 | 11.5 | 3.2 | 13.2 |
| [multiple RDI] | [1.1] | [7.7] | [2.3] | [8.8] |
| Vitamin B12 (μg) | 5.0 | 15.0 | 12.7 | 22.7 |
| [multiple RDI] | [2.5] | [7.5] | [6.3] | [11.3] |

Table 10: Australian nutrient intakes, 35+ year olds

| Nutrient | Mean without energy drinks | Mean with energy drinks | 95th percentile without energy drinks | 95th percentile with energy drinks |
|---|---|---|---|---|
| | National survey | Scenario A | National survey | Scenario A |
| Riboflavin (mg) | 1.9 | 21.9 | 4.0 | 24.0 |
| [multiple RDI] | [1.5] | [11.0] | [3.0] | [12.0] |
| Niacin, preformed (mg) | 8.6 | 48.6 | 21.6 | 61.6 |

Table 11: New Zealand nutrient intakes, 35+ year olds

| Nutrient | Mean without energy drinks | Mean with energy drinks | 95th percentile without energy drinks | 95th percentile with energy drinks |
|---|---|---|---|---|
| | National survey | Scenario A | National survey | Scenario A |
| Riboflavin (mg) | 1.7 | 21.7 | 3.3 | 23.3 |
| [multiple RDI] | [1.3] | [10.9] | [2.5] | [11.7] |
| Niacin, preformed (mg) | 7.2 | 47.2 | 16.2 | 56.2 |
| Vitamin B6 (mg) | 1.4 | 11.4 | 2.9 | 12.9 |
| [multiple RDI] | [1.0] | [7.6] | [2.0] | [8.6] |
| Vitamin B12 (µg) | 4.7 | 14.7 | 11.5 | 21.5 |
| [multiple RDI] | [2.4] | [7.4] | [5.7] | [10.7] |