

29 NOVEMBER 2000
10/01

**NOTICE OF A PROPOSED CHANGE TO FOOD
REGULATION &
FURTHER INVITATION FOR SUBMISSIONS**

APPLICATION 394

**FORMULATED CAFFEINATED BEVERAGES (formerly Energy
Drinks)**

NOTE:

This document expands on the information usually provided as Explanatory Notes. The Full Assessment, as referred to in section 15 of the ANZFA Act, for Application A394 – Formulated Caffeinated Beverages (formerly Energy Drinks) may be obtained from the Standards Liaison Officer (contact details are provided at the end of this document).

INTRODUCTION

The Australia New Zealand Food Authority received an application from *Red Bull GmbH*, manufacturers of the *Red Bull energy drink* on 13 May 1999, to amend the Australian *Food Standards Code* to include appropriate regulatory provisions for 'energy drinks'. In particular the applicant sought permission for caffeine, B complex vitamins and other substances such as taurine, glucuronolactone and inositol to be added to such beverages.

The objective of the application is to develop regulatory provisions for beverages commonly known as 'energy drinks' within the *Food Standards Code(s)*.

The completion date for Application A394 was extended by six months, under Section 35 of the ANZFA Act, in order to enable the relevant findings of an expert working group on caffeine to be incorporated. This group was established for the purposes of considering extended permissions for caffeine in beverages in relation to Application A344 (Caffeine in non-alcoholic beverages) and A394.

A brief description of food standards setting in Australia and New Zealand is given at Attachment 3 to this report.

BACKGROUND

Currently, there is no standard in the Australian *Food Standards Code* or the New Zealand *Food Regulations 1984* for 'energy drinks' such as *Red Bull*. 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). The TTMRA permits the sale of any food legally sold in either Australia or New Zealand to be sold in the other country. Hence 'energy drinks', which are consumed and represented as a food, can be imported into Australia from New Zealand but not legally manufactured in Australia for domestic sale.

'Energy drinks' contain levels of nutritive and other biologically active substances well in excess of levels currently permitted in the *Food Standards Code* both for general purpose foods and special purpose foods.

'Energy drinks' do not have a special dietary function but do have an intended functional effect in relation to real or perceived energy release over and above that achieved by normal dietary intake.

CONSULTATION

A total of 13 submissions were received at Preliminary Assessment (refer to Attachment 7 of the Full Assessment Report for Summary of Submissions, available from the Standards Liaison Officer). The majority of submitters supported development of a standard for regulation of 'energy drinks'. The three exceptions sought more information eg in relation to caffeine consumption, and/or recommended

a more extensive review of the current permissions for nutritive substances and guarana.

As part of the consultative process, an expert external working party also met in May 2000 to comment on particular components of the composition and labelling of 'energy drinks'. Comments from this working group have been considered in finalising the Full Assessment report.

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, as this application addresses a type of product not previously regulated in the Australian *Food Standards Code*, it is necessary to establish underpinning policy principles in order to provide a framework for possible regulation of 'energy drinks'. Therefore, there are a number of policy principles proposed which are specific to this application.

These principles may also serve as the basis for future consideration of other functional or supplemental-type food products.

- 'Energy drinks' are part of a newly defined category of foods (within the current Australian and new joint *Australia New Zealand Food Standards Codes*) which differ from current representations of general purpose and special dietary purpose foods.
- Combinations and levels of ingredients should be based on evidence of safety rather than efficacy or intended purpose, except where considered necessary.
- Health and related claims on 'energy drinks' should be subject to the current prohibitions, or same proposed conditions of substantiation, as health and related claims generally.

ISSUES ARISING FROM THIS APPLICATION

'Energy drinks' exemplify a new type of product being considered for regulatory purposes by ANZFA. The following issues have arisen in the assessment of this application.

Role of the product

This application raises consideration of a type of product, the intent of which goes beyond normal nutritional or special purpose considerations. It is the view of ANZFA that these products are a specific category in their own right and that 'energy drinks' are one example of such products.

For the purposes of this assessment, it is proposed that a new category of product be developed within the current and new *Food Standards Code(s)* and referred to as **Functional Products**, and that the following working definition be adopted:

Functional Products: *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.*

The words ‘real or perceived’ have been added to address claims or intent that may not be readily substantiated by traditional scientific means.

Location of the relevant provisions within the *Food Standards Codes*

Currently, there is no standard in the Australian *Food Standards Code* or the New Zealand *Food Regulations 1984* for ‘energy drinks’ such as *Red Bull*. Furthermore, there are no international precedents.

‘Energy drinks’ are currently manufactured in New Zealand under the *Dietary Supplement Regulations 1985*.

‘Energy drinks’ contain levels of nutritive and other substances well in excess of levels currently permitted in the Australian *Food Standards Code* both for general purpose foods and special purpose food provisions and thereby, do not readily fit within these models either compositionally, or by intent.

It has been necessary in this assessment to consider firstly, if ‘energy drinks’ should be regulated by means of a food standard and if so, the appropriate locations within the current *Food Standards Code* and new joint *Australia New Zealand Food Standards Code*.

Definitions

Definitions need to be considered for both the specific product (‘energy drinks’) and the category of product (‘functional foods’) because:

- common understandings of the terms do not exist; and
- there are specific compositional or labelling provisions required.

Furthermore, there are a variety of definitions being used by manufacturers, government and researchers resulting in confusion and a lack of consistency of approach.

Market suitability

‘Energy drinks’ are marketed as a ‘niche-product’ and have certain characteristics making them unsuitable for the general population.

Compositional permissions

As noted above, a number of the substances added to ‘energy drinks’ differ significantly either by nature or amount from general purpose and special purpose foods. Consideration has been given to safety, and purpose and efficacy of these substances.

Safety

Assessments for safety have been constrained by a paucity of data on a number of the added substances, particularly in relation to the amounts present in the product. Where clinical data are lacking, history of use has been taken into account and a cautionary approach adopted in respect of permissions granted.

Purpose

Purpose has been taken into account only for the characterising ingredient of caffeine. A minimum amount has been prescribed to clearly differentiate between caffeine added for technological function (ie flavour) or for psycho-active effect (eg stimulation).

Efficacy

It has not been considered appropriate to take efficacy into account in relation to compositional requirements. Rather, efficacy has been considered in relation to claims made about the product.

Labelling requirements and claims

As a result of the above considerations, the need for specific labelling has become apparent as a means of risk-management. Labelling requirements are thereby, one of the main issues for consideration.

Claims currently made on the labels for ‘energy drinks’ are subject to the current labelling provisions of the current Australian *Food Standards Code* and New Zealand *Dietary Supplement Regulations 1985*.

It should be noted, that many claims made on labels for ‘energy drinks’ would constitute ‘enhanced function claims’ as described by Proposal P153 – Health and Related Claims and would therefore, be subject to the outcomes of P153 and proposed Standard 1.2.7 of the joint *Australia New Zealand Food Standards Code*. Within this context, some of the claims on formulated caffeinated beverages that are currently on the market would need to undergo a pre-assessment process for continued sale.

Furthermore, vitamin [and mineral] content claims are subject to the provisions of Standards A9 and 1.3.2 in the respective Codes. Formulated caffeinated beverages would not qualify as ‘claimable foods’ under these provisions and therefore, would not be able to make related vitamin and mineral content claims.

PROPOSED REGULATION OF ENERGY DRINKS

Regulation

It is proposed that energy drinks 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 would be Standard R11 in the current *Food Standards Code* and Part 2.11.1 in the *Australia New Zealand Food Standards Code*. In the latter case, this standard would be the first in a new part that may be later expanded to cater for a wider range of dietary supplement or functional-type food products.

Definitions and names

The assessment of this application proposes that ‘energy drinks’ are more appropriately referred to as formulated caffeinated beverages or formulated stimulant beverages. For the purposes of this paper the term **formulated caffeinated beverages** has been used.

It is proposed that a definition for formulated caffeinated beverages be as follows:

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.*

And, that for the purposes of the standard(s), a one-day quantity of formulated caffeinated beverage be defined as:

The amount of that food which is to be consumed in accordance with the direction specified in the label.

Composition

This assessment has 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;
- a minimum amount of caffeine be required in order to differentiate the market/purpose of the product;
- 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 is proposed that energy drinks be permitted to contain the following nutritive and other biologically active substances as maximum amounts in 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 total concentration of 320 mg/L, but should not be less than 145 mg/L.

Labelling

The following requirements are proposed:

- the labels on all formulated caffeinated beverages must declare quantities of energy, carbohydrate, caffeine from all sources and all other added substances (except those present for 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 exemptions/prohibitions are 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].

FURTHER PERMISSIONS

This assessment has considered in detail the substances added to *Red Bull energy drink*. ANZFA recognises that other formulated caffeinated beverages may contain different substances, or different formulations. It is intended that the draft standard be further developed to potentially regulate a broader range of functional beverages.

ANZFA invites submissions with sufficient detail to enable consideration of other substances or ingredients that may contribute to the development of a standard that is potentially more generic than the *Red Bull energy drink* formulation. This would particularly apply to extracted/refined substances where regulatory permission for addition is required.

CONSEQUENTIAL AMENDMENTS

In order to accommodate this new type of product within current regulatory terminology, the definitions of nutritive substances in the new *Australia New Zealand Food Standards Code* will need to be considered in relation to encompassing ‘functional’ as well as ‘nutritional’ roles. Amendments will also be required to the current and new Codes in respect of nutrition labelling requirements (Standard A1(13) and Standard 1.2.8) and additive permissions (Standards A6 and A9).

REGULATORY IMPACT ANALYSIS

Consideration of the Regulatory Impact for this application concludes that the development of a food standard for formulated caffeinated beverages within the current Australian *Food Standards Code* and new joint *Australia New Zealand Food Standards*

Code removes the current inequity with regard to the regulation of ‘energy drinks’ between Australia and New Zealand, and provides the consumer with the most effective regulation to help ensure that public health and safety are not compromised.

Further information in respect of regulatory impact analysis by ANZFA may be found at Attachment 2 to this report.

WORLD TRADE ORGANIZATION NOTIFICATION

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 would be required on the basis of constituting a Technical Barrier to Trade (TBT).

Further information in respect of the WTO notification may be found at Attachment 2 to this report.

INVITATION FOR PUBLIC SUBMISSIONS

In respect of this application, ANZFA specifically invites comment on the draft standard(s) at Attachment 1 to this report, and the related issues outlined below.

1. Policy principles in relation to functional and supplemental-type products that are clearly foods and are not encompassed by the current Australian *Food Standards Code*.

The specific properties of Functional Products that delineate them from general and special purpose foods are that they:

- contain amounts of nutritive and other biologically active substances beyond naturally occurring levels, and beyond levels permitted for general purpose and special purpose foods; and
- may contain novel substances, traditional substances in novel amounts or traditional substances presented in a novel form ie in a food where they would not normally be found.

As a consequence of these properties, and for the purposes of the development of associated regulation, it is proposed that:

- safety assessments be conducted as required for added substances;
- a conservative approach to permissions be adopted;
- a list of positive permissions for ingredients be provided;
- a minimum amount of caffeine be required in order to differentiate the market/purpose of the product;
- claims be subject to the relevant standard(s) for health and related claims; and
- specific labelling advice be required.

2. Definitions

Functional Products:

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.

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.

Discussion on the name of the product is also invited ie formulated **caffeinated** beverages; formulated **stimulant** beverages; or alternative.

3. Compositional requirements

It is proposed that formulated caffeinated beverages contain carbohydrate, caffeine in the amount 145 mg/L to 320 mg/L, and other substances.

Views are particularly sought on:

- the requirement for a minimum caffeine concentration;
- the proposed permitted maximum amounts of added substances per one day quantity; and
- the potential expansion of the scope of the standard.

4. The safety assessments of proposed substances permitted for inclusion in formulated caffeinated beverages. These are detailed in Attachment 3 to the Full Assessment Report, available from the Standards Liaison Officer).

5. Further substances and/or ingredients that may be considered for inclusion in formulated caffeinated beverages as discussed above in 'Further Permissions'.

ANZFA invites submissions with sufficient detail to enable consideration of other substances or ingredients that may contribute to the development of a standard that is potentially more generic than the *Red Bull energy drink* formulation. This would particularly apply to extracted/refined substances where regulatory permission for addition is required.

In respect of such submissions, submitters should refer to the Safety Assessment Report (Attachment 3 of the Full Assessment Report, available from the Standards Liaison Officer) for examples of the type of data required.

The following additional information in relation to products containing these substances or ingredients should also be provided:

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

6. The marketing of formulated caffeinated beverages, particularly in respect of children.

The applicant has stated that children are not intended as a market-target group. However, the availability of formulated caffeinated beverages in supermarkets, petrol stations, milk bars etc mean that children can readily purchase the product, price notwithstanding. ANZFA considers that this incidental availability to children should be managed as effectively as possible and seeks views on possible approaches.

7. Labelling proposals in respect of formulated caffeinated beverages ie that formulated caffeinated beverages be:

- required to provide:
 - an advisory statement regarding presence of caffeine;
 - an advisory statement regarding suitability of product;
 - an advisory statement regarding the beverage consumption limits; and
 - quantitative compositional labelling including energy, carbohydrate, caffeine (from all sources) and other added substances,
- prohibited from bearing a nutrition information panel;
- not permitted to express nutritive substances as a proportion or multiples of recommended dietary intakes or estimated safe and adequate daily dietary intakes, or make related claims;
- able to make health and related claims only in accordance with proposed Standard 1.2.7 (subject to outcomes of Proposal P153); and
- able to use a statement or graphic 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.

Comment is also invited on whether nutrition claims more generally including nutrition function claims, should also be prohibited eg claims in relation to macronutrients, other biologically active substances or energy.

INFORMATION FOR SUBMITTERS

ANZFA has completed a full assessment of the application, prepared a new draft standard to the Australian *Food Standards Code* and the proposed *Australia New Zealand Food Standards Code* and will now conduct an inquiry to consider the new draft standards and their regulatory impact.

Written submissions containing technical or other relevant information which will assist ANZFA in undertaking a full assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. ANZFA's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of ANZFA are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of ANZFA and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to ANZFA, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires ANZFA to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Application A394** at one of the following addresses:

Australia New Zealand Food Authority PO Box 7186 Canberra Mail Centre ACT 2610The Terrace AUSTRALIA Tel (02) 6271 2222 Fax (02) 6271 2278	Australia New Zealand Food Authority PO Box 10559 WELLINGTON 6036 NEW ZEALAND Tel (04) 473 9942 Fax (04) 473 9855
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Submissions should be received by ANZFA by **23 February 2001**.

General queries on this matter and other Authority business can be directed to the Standards Liaison Officer at the above address or by Email on <slo@anzfa.gov.au>. Submissions should not be sent by Email as ANZFA cannot guarantee receipt. Requests for more general information on ANZFA can be directed to the Information Officer at the above address or by Email <info@anzfa.gov.au>.

ATTACHMENTS

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|--------------|---|
| Attachment 1 | Draft Standard R11 and Draft Standard 2.11.1 |
| Attachment 2 | Regulation Impact Statement and World Trade Organization Notification |
| Attachment 3 | Food Standards Setting in Australia and New Zealand |

**DRAFT VARIATION TO THE AUSTRALIAN FOOD STANDARDS CODE
AND THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE**

DRAFT VARIATION TO THE AUSTRALIAN FOOD STANDARDS CODE

To commence: On gazettal

The Food Standards Code and the Australia New Zealand Food Standards Code are varied by –

(1) deleting subclause 5(1) of Standard A6 in the Food Standards Code, substituting

5. (1) Except as permitted in Standards O1, O4 and R11, caffeine must not be added to food.

(2) deleting the first paragraph of the Purpose clause in Standard A9 in the Food Standards Code, substituting -

This Standard regulates the addition of vitamins and minerals to foods, and the claims which can be made about the vitamin and mineral content of foods, other than those special purpose foods standardised in Standards R5, R6, R7, R9 and R10.

(3) inserting immediately following Standard A1(13)(j) in the Food Standards Code -

(k) The label on a package of formulated caffeinated beverage must not bear a nutrition information panel.

(4) inserting immediately following Standard R10 in the Food Standards Code -

STANDARD R11

FORMULATED CAFFEINATED BEVERAGES

Purpose

The purpose of this Standard is to regulate non-alcoholic caffeinated beverages that are intended to provide real or perceived enhanced physiological and/or performance effects.

Table of Provisions

1. Interpretation
2. Composition
3. Labelling

Interpretation

1. In this Standard –

‘formulated caffeinated beverage’ is a non-alcoholic water-based beverage which contains 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.

‘one day quantity’ in relation to formulated caffeinated beverage, is the amount of that food which is to be consumed in one day in accordance with the directions specified in the label.

Composition

2. (1) A formulated caffeinated beverage must contain not less than 145 mg/L and not more than 320 mg/L of caffeine.
3. A formulated caffeinated beverage may contain –
 - (a) colourings;
 - (b) flavourings;
 - (c) modifying agents listed in Table 1 of Standard A10; and
 - (d) the substances listed in column 1 of the Table to this paragraph, provided that the amount of that substance present in the food does not exceed the amount specified in relation to that substance in column 2 of the Table.

TABLE TO PARAGRAPH 3(d)

Column 1	Column 2
Substance	Maximum amount per one-day quantity
Riboflavin	20 mg
Niacin	35 mg
Vitamin B ₆	10 mg
Vitamin B ₁₂	10 µg
Pantothenic acid	10 mg
Taurine	2000 mg
Glucuronolactone	1200 mg
Inositol	100 mg

Labelling

4. (1) The label on or attached to a package of formulated caffeinated beverage must include declarations of the -
- (a) serving size of the food; and
 - (b) quantities, per serving size and per 100 mL of –
 - (i) energy, expressed in kilojoules;
 - (ii) carbohydrate, expressed in grams;
 - (iii) caffeine, expressed in milligrams; and
 - (iv) the substances listed in column 1 of the Table to paragraph 3(d) expressed in the units included in column 2 of the Table.

Editorial note:

An example of the declaration required by subclause 4(1) is set out below

	Per serving	Per 100 mL
Serving size: 250mL		
Energy	510 kJ	205 kJ
Carbohydrate	30 g	12 g
Caffeine	80 mg	32 mg
Riboflavin	10 mg	4 mg
Niacin	35 mg	14 mg
Vitamin B ₆	10 mg	4 mg
Vitamin B ₁₂	10 µg	4 µg
Pantothenic acid	10 mg	4 mg
Taurine	1000 mg	400 mg
Glucuronolactone	600 mg	240 mg
Inositol	100 mg	40 mg

- (2) The label on or attached to a package of formulated caffeinated beverage must include advisory statements to the effect that –
- (a) the food contains caffeine; and
 - (b) the food is not recommended for –
 - (i) children; or
 - (ii) individuals sensitive to caffeine.
- (3) The label on or attached to a package of formulated caffeinated beverage must include an advisory statement in words to the effect of -
- “Consume no more than [amount of one day quantity] per day.”

(4) The label on or attached to 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.

DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

- (5) *deleting paragraph 3(1)(j) of Standard 1.2.8, inserting -*
- (j) in a small package; or
(k) formulated caffeinated beverages.
- (6) *deleting subclause 4(3) of Standard 1.2.8, substituting -*
- (3) Where a nutrition claim is made in relation to a food in a small package, the label must include the information prescribed in clause 8.
- (4) The label on a package of formulated caffeinated beverage must not bear a nutrition information panel.
- (7) *inserting immediately following Standard 2.10.2 of the Australia New Zealand Food Standards Code, the following -*

Standard 2.11.1

Formulated Caffeinated Beverages

Purpose

The purpose of this Standard is to regulate non-alcoholic caffeinated beverages that are intended to provide real or perceived enhanced physiological and/or performance effects.

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Table of Provisions

1	Interpretation
2	Composition
3	Labelling

1 Interpretation

In this Standard –

‘formulated caffeinated beverage’ is a non-alcoholic water-based beverage which contains 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.

‘one day quantity’ in relation to formulated caffeinated beverage, means the amount of that food which is to 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.
- (2) A formulated caffeinated beverage may contain the substances listed in column 1 of the Table to this paragraph, provided that the amount of that substance present in the food does not exceed 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
Riboflavin	20 mg
Niacin	35 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 Labelling

- (1) The label on a package of formulated caffeinated beverage must include declarations of the -
 - (a) serving size of the food; and
 - (b) quantities, per serving size and per 100 mL of –
 - (i) energy, expressed in kilojoules;
 - (ii) carbohydrate, expressed in grams;
 - (iii) caffeine, expressed in milligrams; and
 - (iv) the substances listed in column 1 of the Table to paragraph 3(d) expressed in the units included in column 2 of the Table.

Editorial note:

An example of the declaration required by subclause 4(1) is set out below

	Per serving	Per 100 mL
Serving size: 250 mL		
Energy	510 kJ	205 kJ
Carbohydrate	30 g	12 g
Caffeine	80 mg	32 mg
Riboflavin	10 mg	4 mg
Niacin	35 mg	14 mg
Vitamin B ₆	10 mg	4 mg
Vitamin B ₁₂	10 µg	4 µg
Pantothenic acid	10 mg	4 mg
Taurine	1000 mg	400 mg
Glucuronolactone	600 mg	240 mg
Inositol	100 mg	40 mg

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

- (a) the food contains caffeine; and
- (b) the food is not recommended for –
 - (i) children; or
 - (ii) individuals sensitive to caffeine.

(3) The label on a package of formulated caffeinated beverage must include an advisory statement in words to the effect of -

“Consume no more than [amount of one day quantity] per day.”

(4) 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.

(5) ‘Formulated caffeinated beverage’ is a prescribed name.

REGULATION IMPACT ANALYSIS

ANZFA develops food regulation suitable for adoption in Australia and New Zealand. It is required to consider the impact, including compliance costs to business, of various regulatory (and non-regulatory) options on all sectors of the community which includes the consumers, food industry and governments in both countries. The regulation impact assessment will identify and evaluate, though not be limited to, the costs and benefits of the regulation, and its health, economic and social impacts. In the course of assessing the regulatory impact, ANZFA is guided by the Australian *Guide to Regulation* (Commonwealth of Australia 1997) and *New Zealand Code of Good Regulatory Practice*.

Consideration of the Regulatory Impact for this application concludes that the development of a food standard for formulated caffeinated beverages within the current Australian *Food Standards Code* and new joint *Australia New Zealand Food Standards Code* removes the current inequity with regard to the regulation of 'energy drinks' between Australia and New Zealand, and provides the consumer with the most effective regulation to help ensure that public health and safety are not compromised.

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).

Matters relating to public health and safety are notified as a Sanitary or Phytosanitary (SPS) notification, and other matters as a Technical Barrier to Trade (TBT) notification.

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 would be required on the basis of constituting a Technical Barrier to Trade (TBT).

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. The Australia New Zealand Food Authority is now developing a joint *Australia New Zealand Food Standards Code* which will provide compositional and labelling standards for food in both Australia and New Zealand.

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 the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *Food Regulations 1984*.
- **Food imported into New Zealand from Australia** must comply with either the Australian *Food Standards Code* or the New Zealand *Food Regulations 1984*, but not a combination of both. 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 New Zealand from Australia** must comply with either the Australian *Food Standards Code* or the New Zealand *Food Regulations 1984*, but not a combination of both.
- **Food imported into Australia from New Zealand** must comply with the Australian *Food Standards Code*. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may be imported into Australia from New Zealand if it complies with the New Zealand *Food Regulations 1984* or *Dietary Supplements Regulations 1985*.
- **Food manufactured in Australia and sold in Australia** must comply solely with the Australian *Food Standards Code*, except for exemptions granted in Standard T1.

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*.