

8 August 2001
02/02

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 all 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:

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 Canberra Mail Centre ACT 2610
 AUSTRALIA
 Tel (02) 6271 2258
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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.

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

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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) 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 $\frac{\text{Column 3} \times 1000}{\text{Column 2}}$

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.