

# FOOD REGULATION POLICY OPTIONS PAPER

**The Regulation of Caffeine in Foods**

Produced for the Food Regulation Standing Committee (FRSC)

by the FRSC Caffeine Working Group

August 2013



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# 1 Introduction

This Food Regulation Policy Options Paper has been developed by the Food Regulation Standing Committee's (FRSC) Caffeine Working Group and endorsed by FRSC. Public submissions on the proposed options are now being sought.

The Food Regulation Policy Options Paper, together with the community feedback received, will be provided to the Legislative and Governance Forum on Food Regulation (the Forum)<sup>1</sup> to assist it in formulating policy guidelines in relation to the regulation of caffeine in the Australian and New Zealand food supplies. Food regulation policy guidelines are notified to Food Standards Australia New Zealand (FSANZ) under section 18(3) of the *Food Standards Australia New Zealand Act 1991*. FSANZ is required to have regard to food regulation policy guidelines notified by the Forum in the development or review of food regulatory measures.

Important notice to all submitters: All submissions are subject to the Freedom of Information Act 1982 in Australia and the Official Information Act 1982 in New Zealand. If you consider that all or part of your submission should not be released, please make this clear when making your submission and indicate the grounds for withholding the information.

A general summary of submissions will be produced and published at the [Food Regulation Secretariat website](#) and the [New Zealand Food Safety website](#)

Copyright in an original submission resides with the copyright owner of that submission, but the act of making a submission will grant the Australian Government and the New Zealand Government a licence to use the submission for the purpose of making a summary of the submission for the website and for future policy or standard development work.

## **Electronic submissions via e-mail are preferred.**

Submissions should be provided **using the response form provided (Appendix 1)**, or in a similar format, **by 6pm on Friday 18 October 2013 to:**

*Australian resident's submissions:*

Via **email** to the [Food Regulation Secretariat](#):

Or via post: Submissions – Caffeine Options Paper Consultation, C/- Food Regulation Secretariat, PO Box 4, WODEN ACT 2606; or fax: (02) 62895100.

*New Zealand resident's submissions:*

Via **email** to the [Caffeine Review](#)

Or via post: Submissions – Caffeine Options Paper Consultation, C/- Lisa Ralph, Senior Analyst, International Policy, Ministry for Primary Industries, PO Box 2526, Wellington 6140.

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<sup>1</sup> Convening as the Australia and New Zealand Food Regulation Ministerial Council

## 2 Useful definitions

**Added caffeine** means caffeine added in its chemical form to foods.

**Caffeine** is a white crystalline xanthine alkaloid with stimulant effects in humans.

**Encapsulation techniques** refers to food technologies that allow substances to be mixed into foods without the substance interacting with the other components of the food.

**Energy drink** refers to a non-alcoholic caffeine containing beverage typically consumed to provide an ‘energy boost’ or for mental alertness.

**Energy shot** refers to small volume concentrated liquid containing caffeine and other ingredients.

**Formulated caffeinated beverages** (FCBs) is the regulatory category for ‘energy drinks’ sold in Australia and New Zealand.

**Food Regulation Standing Committee** (FRSC) is the committee of senior officials from the Australian States, Territories and Commonwealth, and New Zealand responsible for food regulation policy, and reports to the Legislative and Governance Forum on Food Regulation.

**Food Standards Australia New Zealand** (FSANZ) is the trans-Tasman agency responsible for, principally, developing food standards and variations of food standards for Australia and New Zealand.

**Implementation Subcommittee for Food Regulation** (ISFR) is the committee of senior officials from the Australian States, Territories and Commonwealth, and New Zealand responsible for promoting consistent implementation of food regulation in Australia and New Zealand.

**Legislative and Governance Forum on Food Regulation** (Forum) is the committee of Ministers from the Australian States, Territories and Commonwealth, and New Zealand responsible for food regulation policy and for considering standards and variations to standards developed by Food Standards Australia New Zealand (FSANZ).

**Naturally occurring caffeine** is caffeine that is present as a bound chemical in a plant or plant product used as food for humans.

**Policy Guideline** means a guideline provided by the Legislative and Governance Forum on Food Regulation to Food Standards Australia New Zealand under section 18(2)(e) of the Food Standards Australia New Zealand Act 1991.

### 3 Purpose

In 2003, the then Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) now known as the Legislative and Governance Forum on Food Regulation (the Forum) issued the Ministerial Council Policy Guideline on the Addition of Caffeine to Foods (the Ministerial Council Policy Guideline; Appendix 2). Since that time, the number and variety of products containing caffeine on the market has increased. There is some public concern that this increase in the range of products may be associated with increased dietary exposure to caffeine, particularly among children and adolescents, and that increased dietary exposure may have implications for individual and population health.

In light of the range of products currently on the market and potential future developments, the Ministerial Council asked FRSC to review the Ministerial Council Policy Guideline.

In particular, there is concern that the Ministerial Council Policy Guideline is ambiguous and lacks clarity. As such it may not provide adequate guidance for regulators for the risk management of caffeine in the food supply.

The purpose of this consultation paper is to establish if the Ministerial Council Policy Guideline needs to be updated, maintained or rescinded in order to provide FSANZ with appropriate guidance to assist in the development or review of food standards relating to caffeine in 'food'. It provides a background on the regulation of caffeine in Australia and New Zealand, provides information on caffeine consumption and exposure and a summary of research on the health effects of caffeine.

This paper sets out the problem that the review of the Ministerial Council Policy Guideline is intended to address and options to address the problem.

While this paper discusses the standards that currently regulate the addition of caffeine in food in Australia and New Zealand, the options presented relate only to the Ministerial Council Policy Guideline and not to the standards themselves. It should be emphasised that any decision on the future of the Ministerial Council Policy Guideline does not necessarily trigger a review of the standards by FSANZ. The regulatory standards for caffeine are outside the scope of this review. The issue of mixing alcohol with energy drinks is also outside the scope of this review and is being investigated separately by the Intergovernmental Committee on Drugs and FRSC.

## 4 Background

### 4.1 A HISTORY OF THE REGULATION OF CAFFEINE

The use of added caffeine in food is regulated in Australia and New Zealand by the Food Code, and also in New Zealand by the New Zealand Food (Supplemented Food) Standard 2010 (the Supplemented Food Standard). Foods that naturally contain caffeine (e.g. coffee, tea, chocolate, guarana) are generally permitted and, with few restrictions, can be mixed with other foods under the general provisions of the Food Code.

Prior to 2001, the only permission in the Food Code to add caffeine to food was in the context of caffeine as a food additive (flavouring) in kola-type<sup>2</sup> beverages. In 2001 FSANZ (then the Australia New Zealand Food Authority) amended the Food Code to permit the production and sale of formulated caffeinated beverages (FCBs). This was as a result of an application from an energy drink manufacturer for specific permissions in the Food Code for its type of product.

At the time, energy drinks were sold in New Zealand under the provisions of the New Zealand Dietary Supplements Regulations 1985 and in Australia under the operation of the Trans-Tasman Mutual Recognition Arrangement (TTMRA). TTMRA is a bilateral arrangement between Australia and New Zealand which provides that products legally able to be sold in one country can be legally sold in the other.

The 1999 application (A394) that triggered the development of permission for the use of caffeine in FCBs used the term 'energy drinks' which, while not appearing in regulations, continues in common usage by industry and regulators.

### 4.2 CURRENT REGULATION OF CAFFEINE IN AUSTRALIA AND NEW ZEALAND

#### 4.2.1 The Ministerial Council Policy Guideline on the Addition of Caffeine to Foods

At its meeting in May 2002, the then Ministerial Council agreed to develop a Policy Guideline on the addition of caffeine to foods. It was agreed that the Policy Guideline would take account of the health, safety and behavioural aspects of foods with added caffeine and the views of the food industry. Following stakeholder consultation, the Ministerial Council issued the Ministerial Council Policy Guideline (Appendix 2).

The purpose of the Ministerial Council Policy Guideline was to ensure that, in developing or reviewing food regulatory measures, FSANZ has regard to the principle of limiting the exposure of vulnerable individuals to foods containing caffeine.

The Ministerial Council Policy Guideline states that until further evidence becomes available, caffeine regulation (as currently in place in Australia) should maintain the status quo by:

- maintaining the current additive permissions for caffeine; and
- restricting the use of new products containing non-traditional caffeine-rich ingredients (including guarana) to boost the caffeine content in other food, beyond the current provisions for caffeine.

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<sup>2</sup> “Kola” is intentionally spelt with a “k”, in this paper, to differentiate it from branded products.

## 4.2.2 The Australia New Zealand Food Standards Code

Food regulation in Australia is developed and applied under the Food Regulation Agreement between the States, Territories and Commonwealth. New Zealand joined this arrangement in 1995 with the signing of the *Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* (the Food Treaty). Food regulation relating to composition and labelling for both countries is set out in the Food Code, which was issued in 2000. The Food Code is developed and maintained by FSANZ.

Under the Food Code, caffeine is expressly permitted for use in kola-type beverages (as a food additive) and in FCBs. The addition of caffeine to foods is regulated under the following standards in the Food Code:

### Standard 1.3.1 – Food additives

“Food additive” is described in the Purpose statement of Standard 1.3.1. It reads:

*A food additive is any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule.*

Food additives must be approved by FSANZ and listed in Standard 1.3.1 before they can be used in food for sale in Australia and New Zealand. Caffeine is permitted for use as a food additive (flavour) in kola-type beverages only (see Schedule 1 of Standard 1.3.1).

The total caffeine content of kola-type beverages must not exceed 145 mg/L.

### Standard 2.6.2 – Non-alcoholic beverages and brewed soft drinks

Clause 9 (2) of this standard prohibits the presence of caffeine in products that meet the definition of ‘formulated beverage’. However, there is no prohibition or express permission for the use or presence of caffeine in products defined as ‘electrolyte drinks’ in Clause 6 of Standard 2.6.2.

### Standard 2.6.4 – Formulated caffeinated beverages

As noted above, this Standard was developed following an application from an energy drink company in 1999 (A394) to amend the Food Code to include appropriate regulatory provisions for ‘energy drinks’.

Under Standard 2.6.4 FCBs must contain no less than 145 mg/L and no more than 320 mg/L of caffeine, including caffeine from guarana. Standard 2.6.4 requires the label of a FCB to state the quantity of caffeine in mg/100mL and mg per serving size. The label on a FCB must also include advisory statements to the effect that: a) the food contains caffeine; b) the food is not recommended for children, pregnant or lactating women and individuals sensitive to caffeine; and, subject to containing certain substances beyond caffeine, c) no more than a certain amount should be consumed per day.

### Standard 1.2.3 - Mandatory warning and advisory statements and declarations

Any food or beverage that contains guarana or its extract must have a statement on its label that the product contains caffeine. The precise source and amount of caffeine is not required to be specified. However, guarana must be listed in the ingredients list. Kola-type beverages

that contain added caffeine, and foods in which such kola-type beverages are used as ingredients, must also provide a statement to the effect that the product contains caffeine. Subclause 2(2) of this standard also sets out requirements for unlabelled foods in respect of these advisory statements.

#### Standard 1.2.4 – Labelling of ingredients

Where caffeine is added to a food it must be declared in the ingredient list as ‘caffeine’.

Caffeine is naturally present in many foods including coffee and cocoa. Information about the presence or amount of caffeine is not required on the labels of these foods. Foods with naturally occurring caffeine may also be used as ingredients in other foods thereby introducing caffeine into foods where it may not normally be present, and without triggering a requirement for labels to declare the presence of caffeine. The exception is guarana which may also be used as an ingredient in other foods, and also triggers a requirement for a statement to the effect that the product contains caffeine.

While caffeine is also present in a number of sports-type foods and supplements, Standard 2.9.4 – Formulated Supplementary Sports Foods of the Food Code is silent on the presence of caffeine in sports foods.

### **4.3 NEW ZEALAND FOOD (SUPPLEMENTED FOOD) STANDARD 2010**

In New Zealand, the Supplemented Food Standard may apply to products containing caffeine if those products meet the definition of ‘supplemented food’.

A supplemented food is ‘a product represented as a food that has a substance or substances added to it or that has been modified in some way to perform a physiological role beyond the provision of a simple nutritive requirement’<sup>3</sup>. However, some products are specifically excluded from being supplemented foods including products that meet the definition of ‘FCB’ in Standard 2.6.4 of the Food Code.

There is no restriction on the level of caffeine that may be added to a supplemented food under the Supplemented Food Standard. However, this Standard requires that if the supplemented food contains a level of caffeine greater than is required to achieve a technological function under conditions of Good Manufacturing Practice, certain advisory statements (identical to those required under Standard 2.6.4) must be present on the label and the average quantities of caffeine per serve and per 100ml (or 100g) must be declared in the nutrition information panel (see clause 14 of the Supplemented Food Standard). This includes added and naturally occurring caffeine.

The Supplemented Food Standard was developed to provide updated regulatory provisions for food-type products formerly regulated under the Dietary Supplements Regulations 1985. When the Food Code was introduced in 2000, Australia and New Zealand agreed that the Dietary Supplements Regulations would be retained until appropriate provisions for food-type dietary supplements were developed in the Food Code. The Supplemented Food Standard is therefore intended as an interim measure. FSANZ raised a proposal in 2002 to consider the integration of food-type dietary supplements into the Food Code (see Proposal P235). The work on this is on hold pending completion of related work.

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<sup>3</sup> Clause 6, New Zealand (Supplemented Food) Food Standard 2010

Supplemented foods can be imported from New Zealand and sold in Australia under the provisions of TTMRA. Energy shots are one example of a product containing caffeine currently regulated under the Supplemented Food Standard.

#### 4.4 INDUSTRY SELF-REGULATION

Government regulation applies to all manufacturers, importers and retailers of food sold in Australia and New Zealand. Peak beverage industry bodies in Australia and New Zealand have also developed self-regulatory initiatives to assist their members in complying with regulatory requirements and for quality purposes. While these self-regulatory codes only formally apply to members of those organisations, their existence and application across the market may also affect the behaviour of non-members that are aware of them. Key industry self-regulatory initiatives relevant to caffeine include marketing codes for energy drinks and energy shots.

The Australian Beverages Council and the New Zealand Juice and Beverages Association have adopted an 'Industry Commitment', (Australian Beverages Council Ltd) which supports a responsible approach to the marketing, promotion and consumption of energy drinks in order to ensure these products are not available in primary and secondary schools, are not promoted for mixing with any other beverage, are not marketed or advertised directly to children, and do not promote activities that encourage excessive consumption of energy drinks. The commitment also addresses further issues in relation to energy drinks and alcohol.

Both industry associations also subscribe to an Industry Code for the Manufacturing and Marketing of Energy Shots. This Industry Code specifies that adults are the target market for these products, and requires that energy shots do not exceed 160 mg caffeine per shot. The Industry Code also suggests that retailers ensure that advisory statements are visible on packaging and that products are not positioned near items of interest to children such as confectionery. Advisory statements on energy shots (similar to those on FCBs) are required under the Supplemented Food Standard.

**Question 1: Can you provide any evidence about the level of compliance with and/or effectiveness of these industry codes?**

#### 4.5 OVERSEAS REGULATION OF CAFFEINE

Like Australia and New Zealand, the United States and Canada regulate caffeine as a food additive. In the European Union it is specifically identified and regulated as a flavouring.

Labelling requirements vary internationally, with the European Union requiring caffeine to be mentioned by name in the list of ingredients. Beverages (other than tea and coffee) that contain more than 150 mg/L of caffeine must be labelled with the statement 'high caffeine content' and the quantity of caffeine expressed in milligrams per 100mL.

The European Food Safety Authority is currently undertaking an extensive literature search and review as part of a safety assessment for caffeine. This work was proposed to commence in March 2013 and take a period of six months. This information will be used to conduct a scientific opinion on the safety of caffeine; a deadline for completion of the scientific opinion has not yet been determined (European Food Safety Authority, 2013).

Canadian legislation requires caffeine to be listed as an ingredient if it has been added separately to the product as a pure ingredient. In October 2011, Health Canada published their

proposed approach to managing energy drinks. It was proposed that a maximum limit for total caffeine be set at 400 mg per litre and a maximum amount of caffeine not to exceed 180 mg per container (in the form of a single-serve or multi-serve re-sealable container). In response to stakeholder consultation, Health Canada has confirmed their approach in terms of maximum limits of caffeine for single and multi-serves of energy drinks. Health Canada is in the process of finalising their approach and are yet to implement change to food regulation.

In the United States, any food product that contains added caffeine must list caffeine as an ingredient, but the actual quantity of caffeine does not have to be stated on the label.

Further information about the international regulation of caffeine overseas and the specific regulation of energy drinks can be found at Appendix 3.

**Question 2: Are there any international regulations of relevance that have not been provided here or in Appendix 2? If so, please provide references.**

#### 4.6 THE CHANGING PRESENCE OF CAFFEINE IN THE FOOD SUPPLY

Caffeine can be present in the food supply through four discrete routes:

- Caffeine as a food additive (e.g. to kola-type beverages)
- Caffeine that naturally occurs in food (e.g. tea, coffee and cocoa)
- Caffeine-rich ingredients added to foods (e.g. guarana in energy drinks, coffee in chilled milk)
- Caffeine added to energy drinks and sports foods as an ingredient.

The main product categories that contain caffeine include:

- Coffee
- Teas (containing caffeine)
- Kola drinks
- Energy drinks
- Chocolate and chocolate products
- Sports foods (e.g. energy gels and sports powders)
- Energy shots.

Caffeine levels in kola-type beverages and energy drinks are limited by regulations in the Food Code and therefore have presumably remained reasonably constant since the introduction of the Ministerial Council Policy Guideline in 2003. However newer products introduced to the market since 2003, such as energy shots, have generally contained more caffeine by volume than many other caffeine containing products ([see Tables 1a-1e](#)).

In 2002, FSANZ commissioned an analytical program to determine concentrations of caffeine, whether naturally occurring or added, in a variety of caffeine containing foods and beverages in Australia. Approximately 40 foods (including coffees, teas, soft drinks, energy drinks, flavoured milks, chocolates, ice creams, cakes/biscuits, muesli bars, breakfast cereals, toppings, spreads and beverage bases) were analysed as part of this program. FSANZ published the data collected from this program in NUTTAB 2006 and NUTTAB 2010. The New Zealand Institute of Plant and Food Research (Plant and Food Research) in New Zealand provides caffeine concentration data which is accessible online (the New Zealand Institute of Plant & Food Research, 2012). Plant and Food Research has recently estimated caffeine

concentrations of various café styled coffees available for sale in New Zealand. These are published in FOODFiles version (2012).

Caffeine levels of some of these foods (either based on analytical, label or recipe data) that are currently available for sale, or have been available for sale in the past are included in Tables 1a to 1e.

### Tables 1a-1e: Comparison of caffeine content in a range of products

Table 1a: Comparison of the caffeine content in energy shots

Energy shots	Caffeine content (mg/100ml)
Red Bull energy shot*	133
Monster energy shot*	158
V Pocket Rocket energy shot (based on label claim)	200

Table 1b: Comparison of the caffeine content in energy drinks

Energy drinks	Caffeine content (mg/100ml)
V#	28.3
Powerade Fuel Plus±	32.0
Rockstar±	32.0
Red Bull±	32.0
Monster±	32.0
Mother±	32.0

Table 1c Comparison of the caffeine content in kola-type beverages

Kola-type beverages	Caffeine content (mg/100ml)
Coke Zero%	9.5
Coca Cola#	9.0
Mountain Dew <sup>(NZ)^</sup>	13.5
Mountain Dew <sup>(Aus)^</sup>	15.0
Pepsi <sup>i%^</sup>	10.7
Pepsi Max <sup>%^</sup>	12.0

Table 1d: Comparison of the caffeine content in coffee and tea beverages

Coffee and Tea Beverages	Caffeine content (mg/100ml)
Tea, black, brewed#	22.5
Tea, green, brewed#	12.1
Coffee, cappuccino, double shot, 285ml takeaway cup, café variety#	101.9
Coffee, flat white, double shot, 285ml takeaway cup, café variety#	86.9
Coffee, longblack, double shot, 285ml takeaway cup, café variety#	74.7
Coffee, mocchaccino, double shot, 300ml takeaway cup, café variety#	97.4
Coffee, from ground coffee beans, espresso style@	194.0

Table 1e: Comparison of the caffeine content in confectionery

Confectionery (Chocolate)	Caffeine content (mg/100ml)
Chocolate, milk, with added milk solids <sup>@</sup>	20.0
Chocolate, dark, high cocoa solids <sup>@</sup>	59.0

**Notes to Tables 1a-1e**

\* (No longer available for sale on the Australia and New Zealand market)

<sup>^</sup> New Zealand Institute of Plant and Food Research Limited (2010)

<sup>#</sup> New Zealand Institute of Plant & Food Research Limited (2012)

<sup>±</sup> Department of Health and Ageing (2012a)

<sup>@</sup> Food Standards Australia New Zealand (2010)

<sup>%</sup> Energy Fiend (2013)

<sup>^</sup> Provided by manufacturer

## 4.7 CHANGES IN VOLUME AND TYPES OF PRODUCTS CONTAINING CAFFEINE

Since the Ministerial Council Policy Guideline was issued in 2003 the market for products containing caffeine has changed considerably. The most significant changes have been seen in increases in sales of energy drinks and a coffee-consuming culture outside of the home.

Sales of energy drinks in Australia and New Zealand increased from 34.5 million litres in 2001 to 155.6 million litres in 2010 (Canadean, 2011). In its first ten years, the energy drinks sector in Australia grew faster than any of the other beverage-based categories (soft drinks, water and sports drinks). This growth represents a 25 per cent increase in value, to a total annual value of \$593 million and a 23 per cent share of the total beverages in the convenience category (Convenience & Impulse Retailing, 2010).

This trend is not isolated to Australia, with the global volume of energy drinks consumed increasing to 3.9 billion litres in 2008, almost double the volume sold in 2003. This represents an average increase year on year of 14 per cent. In the Australasia region, volumes increased by 33 per cent, with consumption per person equivalent to approximately 4.2 litres per year. It was estimated that the global market would reach 5.8 billion litres by 2013 (Palmer, 2009).

Coffee consumption is also increasing, with 2010 data suggesting that consumers globally spend a total of \$10.7 billion per year on coffee, equivalent to 2.4 kilograms of coffee per person per year (Knight, 2010).

The sales of other caffeine containing products such as teas and chocolates have not followed the same pattern. For instance, the consumption of chocolate in Australia has remained stable at approximately six kilograms per person per year in 2012 (Paish, 2012), while consumers are drinking more non-caffeinated teas. Over a ten year period to 2008 sales of fruit infusions/herbal teas and green teas grew by five per cent, with negligible growth in black teas (Westwick-Farrow Pty Limited, 2010).

As well as changes across established food and beverage product categories, a number of novel products containing caffeine have been introduced to international markets since 2003. Examples include chewing gums and corn chips containing caffeine.

Following removal of caffeine from the World Anti-Doping Agency's list of prohibited substances in 2004 (Burke and Deakin, 2006), there has been a trend to add caffeine to sports foods, including energy gels and sports powders, for the purpose of enhancing sports performance. Some of these products are currently being sold on the Australia-New Zealand

market as Formulated Supplementary Foods under the Food Code or as supplemented foods under the Supplemented Food Standard.

In 2009, the New South Wales Food Authority (the Authority) conducted a survey on the caffeine content of caffeine-containing drinks. The survey included samples of coffee products, energy drinks, pre-mixed spirits and soft drinks and identified a significant number of products that exceeded the maximum level of caffeine permitted by the Food Code (where restrictions apply) (New South Wales Food Authority, 2010).

In February 2011, following significant efforts to establish consistent national compliance policy and enforcement work with industry, the Authority re-tested energy drinks produced by a range of companies to determine compliance with the Food Code. The Authority found that approximately half of the products that were non-compliant in 2009, were no longer on the market and all products tested complied with the Food Code in terms of both the level of caffeine content and product labelling (New South Wales Food Authority, 2012).

<b>Question 3: Are there any other relevant data not provided here? If so, please provide details and references</b>
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#### 4.8 USE OF CAFFEINE-CONTAINING INGREDIENTS IN FOODS

Foods that contain naturally occurring caffeine, such as coffee, tea, and cocoa, can be used as ingredients or mixed with other foods. Examples include iced coffee and iced tea drinks and chocolate products. There are also indications of an increasing use of the herbal substance guarana in various foods and beverages. However, the actual extent of its use in Australia and New Zealand is not known. Guarana, a naturally rich source of caffeine (3-6 per cent dry weight), is produced from the berries of the plant *Paullinia cupana*, which is native to Central Amazonia in Brazil (Meurer-Grimes, et al., 1998). It is considered a food ingredient and as such there are no restrictions on its use in other foods. The types of foods that currently contain guarana include energy drinks, soft drinks, snacks, sports foods and beverages. Products containing guarana must be labelled with a statement that the product contains caffeine.

To assist in filling the data gaps in relation to the use of guarana in food, an analytical survey has recently been completed on the caffeine content of guarana-containing foods in Australia and New Zealand as part of survey work being undertaken by FRSC's Implementation Sub Committee for Food Regulation (ISFR). These results will be used in conjunction with food consumption data to better estimate the caffeine intakes of the Australian and New Zealand populations, including for higher risk population groups, such as children, adolescents, and pregnant or lactating women.

#### 4.9 SUGAR IN FOODS CONTAINING CAFFEINE

FRSC has noted concerns about possible associations between increased intakes of caffeine and increased intakes of sugar from caffeinated beverages. A study by Keast et al (2011) asked whether the removal of caffeine from sugar-sweetened beverages would also allow the removal of sugar, and suggested that the extra energy in sugar-sweetened beverages (as a result of caffeine's effect on sweetness) may be associated with adult and child weight gain. This association assumes there is an increased use of sugar to 'mask' the bitterness of caffeine in certain beverages. However a preliminary comparison between the amount of sugar in caffeinated products, such as energy drinks and kola-type beverages, with non-caffeinated

products, such as juice and non-caffeinated soft drinks, ([see Tables 2a-2d](#)) shows no difference in the amount of sugar per 100ml.

#### Tables 2a-2d: Sugar content of beverages that are caffeinated and non-caffeinated

Table 2a: Sugar content of energy drinks

Energy drinks	Sugar content (g/100ml)
V#	9.2
Red Bull±	11.0
Monster±	11.4
Mother±	10.4

Table 2b: Sugar content of kola-type beverages

Kola-type beverages	Sugar content (g/100ml)
Coca Cola#	10.9
Pepsi±	10.6
LA Ice±	11.4
Mountain Dew±	12.5

Table 2c: Sugar content of non-caffeinated soft drinks

Non-caffeinated soft drinks	Sugar content (g/100ml)
Schweppes Lemonade±	11.0
Fanta (orange)	11.3
Lift	11.0
Old Stoney Ginger Beer	12.5
Lucozade#	14.0
Ginger ale#	10.8

Table 2d: Sugar content of fruit juice

Fruit juice	Sugar content (g/100ml)
Just Juice, orange and apple , unsweetened#	10.4
Golden Circle Apple and Blackcurrant juice#	9.6
Freshup, apple and orange, unsweetened#	10.6
Coles apple juice±	10.9

Notes to Tables 2a-2d:

# New Zealand Institute of Plant and Food Research (2012)

± Department of Health and Ageing (2012a)

**Question 4: Can you provide any additional information about the use of caffeine as an ingredient in foods and/or the formulation of products using caffeine or caffeine containing ingredients. If so, please provide details.**

## 4.10 CONSUMER BEHAVIOUR AND DIETARY INTAKES OF CAFFEINE

### 4.10.1 Caffeine consumption

Changes in composition or sales data of caffeine-containing products may indicate changes in caffeine consumption, either by the population generally, or by specific population subgroups.

An increase in the number of coffee shops and a prominent ‘coffee culture’ suggest likely increases in caffeine consumption from foods with naturally occurring caffeine by the population generally. In 2002-03, there were 4,364 cafes and coffee shop businesses in Australia. By 2011-12 this had grown to 6,261 (Rowley, 2011). Espresso coffee is now available almost anywhere at any time across a range of outlets, including sporting facilities, bookshops, libraries, and drive-through cafes, as well as at traditional cafes, bars and restaurants. More than one billion cups of coffee are consumed in cafés, restaurants and other outlets each year. This is an increase of 65 per cent over the preceding 10 years (Australian Coffee Traders Association Incorporated, 2006). However, it is not known if this reflects higher individual daily intake of caffeine, or a larger number of consumers, or both.

#### *Australia*

In 2007, the Australian National Children’s Nutrition and Physical Activity survey ([see Table 3a](#)) was used to estimate average daily consumption of caffeine containing products by children and adolescents. As shown in [Table 3a](#), the survey showed a higher (approximately double) caffeine consumption between the 9-13 and 14-16 year age group. Up to date information on caffeine intakes for the Australian population aged 2 years and over will be available from the 2011-13 Australian Health Survey, with results due to be released by the Australian Bureau of Statistics late 2013.

The major sources of caffeine are shown in [Table 3b](#), the major sources of caffeine for young children 2-3 years was chocolate based confectionery (21.7 per cent), for children 4-13 years it was soft drinks (25.7-36.7 per cent) and for older children 14-16 years it was coffee (32.3 per cent).

Table 3a: Mean caffeine intake of Australian children and adolescents by age group and gender. (Commonwealth of Australia, 2008)

Age group	Gender	Mean (mg/day)
2- 3 years	Male	3.4
	Female	3.3
	<b>All</b>	3.4
4-8 years	Male	8.5
	Female	7.7
	<b>All</b>	8.1
9-13 years	Male	19.7
	Female	18.7
	<b>All</b>	19.2

14-16 years	Male	46.8
	Female	36.4
	<b>All</b>	41.7

**Table 3b: Proportion of total caffeine intake from selected food groups: all children by age group\* (Department of Health and Ageing, 2012b)**

Food Group	All children by age group (years)			
	2-3	4-8	9-13	14-16
<b>Non-alcoholic beverages</b>	49.1	55.6	75.2	84.7
Tea	18.8	18.9	17.3	16.9
Coffee and coffee substitutes	4.8	2.4	15.7	32.3
Soft drinks, and flavoured mineral waters	17.5	25.7	36.7	29.6
Electrolyte, energy and fortified drinks	0	2.5	1.2	3.8
Other beverage flavourings and prepared beverages	8.1	6.2	4.3	2.1
<b>Cereals and cereal products</b>	1.5	1.7	1	0.3
Breakfast cereals and bars, unfortified and fortified varieties	1.5	1.5	0.8	0.3
<b>Cereal based products and dishes</b>	13.9	10.5	5.7	2.7
Sweet biscuits	4.9	4.1	2.1	1.3
Cakes, buns, muffins, scones, cake-type desserts	8.8	6.3	3.5	1.4
<b>Milk products and dishes</b>	9.3	8.8	7	6.1
Frozen milk products	3.2	2.5	1.6	0.6
Flavoured milk	3.8	4.7	4.7	5.2
<b>Sugar products and dishes</b>	3.5	2.6	1.3	0.6
Sugar, honey and syrups	1.5	1	0.4	0.4
Jam and lemon spreads, chocolate spreads, sauces	1.8	1.6	0.9	0.2
<b>Confectionery and cereal/nut/fruit/seed bars</b>	22.5	20.5	9.8	4.5
Chocolate and chocolate-based confectionery	21.7	19.9	9.4	4.4

**Note to Table 3b**

Table 3b shows key dietary contributors to total caffeine intake. Foods contributing less than 1.5 per cent to total caffeine intake have not been listed.

The 2011-13 Australian Health Survey will provide updated data on food and beverage consumption by age group, with results due to be released in late 2013.

## 4.10.2 Caffeine intakes

Analysis of consumption data from the 2002 New Zealand National Children's Nutrition Survey data by the New Zealand Institute of Environmental Science and Research Limited (ESR) (Institute of Environmental Science and Research Limited, 2010) identified that the mean caffeine intake of children 5-12 years of age was 20 mg/day and the mean caffeine intake per kg body weight per day as 0.6 mg (see Table 4).

Unpublished analysis of the 2008/09 National Adults Nutrition Survey consumption data by the Ministry for Primary Industries found that 90.6 per cent of adults over 15 years of age consume caffeine in some form. Males 51 – 70 years of age were the highest consumers of caffeine (mean intake 264 mg/day) with males 31 – 50 years of age following close behind (mean intake 253 mg/day). In terms of mean caffeine intakes per kg body weight per day, females 31-50 years of age consume more caffeine than other age and gender groups (3.5 mg/kg/bw/day). The top three highest consumers of caffeine, indicated by the 95<sup>th</sup> percentile, were 19 – 30 year old males (634 mg/day) and 31 – 50 year old females and males equally (614 mg/day). Overall, 37.3 per cent of New Zealand adults over 15 years of age consumed more than 3 mg caffeine per kg body weight per day.

Table 4: Estimated caffeine intakes of New Zealand children<sup>^</sup> and adults<sup>#</sup>

Age group (years) <sup>†</sup>	Gender	Mean (mg/day)	Median (mg/day)	5 <sup>th</sup> percentile (mg/day)	95 <sup>th</sup> percentile (mg/day)	Mean caffeine/kg/bw/day (mg)	% Caffeine intakes >3mg/kg/bw/day
All New Zealand children 5-12 yrs <sup>*^</sup>	All	20	7	1	74	0.6	NA
15 - 18 yrs <sup>#</sup>	Male	75	37	2	258	1.1	7.3
	Female	77	39	1	288	1.2	11.5
19 - 30 yrs <sup>#</sup>	Male	194	120	2	634	2.4	25.7
	Female	144	100	2	413	2.2	22
31 - 50 yrs <sup>#</sup>	Male	253	205	12	614	3	39.7
	Female	252	203	22	614	3.5	47.8
51 - 70 yrs <sup>#</sup>	Male	264	232	55	573	3.1	45.1
	Female	212	184	18	468	3	43.6
71+ yrs <sup>#</sup>	Male	216	208	27	433	2.7	34.9
	Female	179	162	40	360	2.7	36.2
All New Zealand adults (>15 yrs) <sup>#</sup>	All	216	171	5	557	2.8	37.3

## Notes to Table 4:

<sup>†</sup>Data is not available for the 13-14 year age group.

<sup>\*</sup> New Zealand Institute of Environmental Science and Research Limited, 2010

<sup>^</sup> Data based on consumers of caffeine only from the 2002 New Zealand Children's National Nutrition Survey data

# Data based on consumers of caffeine only from the 2008/09 National Adults Nutrition Survey data modelled by the New Zealand Ministry for Primary Industries (unpublished)  
 NA = not available

### 4.10.3 Key caffeine contributors

Analysis of consumption data from the 2002 New Zealand National Children’s Nutrition Survey data by ESR (Institute of Environmental Science and Research Limited, 2010) found the three main dietary contributors of caffeine for children 5 – 12 years of age were: tea (32 per cent), soft drinks (30 per cent) and biscuits, cakes, muffins and pastries (11 per cent); and for children 13 – 15 years of age: soft drinks (32 per cent), tea (29 per cent) and coffee (23 per cent). Energy drinks provide two and three per cent of caffeine in the diet of 5 – 12 year olds and 13 – 15 years old respectively.

Unpublished analysis of the 2008/09 National Adults Nutrition Survey consumption data by the Ministry for Primary Industries found that the main food contributors of caffeine intakes for adult males and females aged 15 – 18 years were soft drinks (23 and 18 per cent); biscuits, cakes, muffins and pastries (18 and 22 per cent); and coffee (17 and 15 per cent). For males and females aged 19 – 30 years, coffee (40 and 38 per cent), soft drinks (17 and 12 per cent) and tea (13 and 21 per cent) were the three main caffeine contributors. Energy drinks were a source of caffeine in eight per cent and six per cent of 19 – 30 year olds males and females respectively. For adults over 31 years of age, coffee (38 – 56 per cent) and tea (26 – 58 per cent) were the main contributors to caffeine intakes ([refer Table 5](#)).

It is important to note that some foods which have a relatively low concentration of caffeine compared to other foods can be a major source of caffeine in the diet primarily due to the proportion of people within an age group consuming it and/or the amount of food or beverage consumed. For example, caffeine containing soft drinks may have a lower concentration of caffeine than some foods, but because of the wide consumption amongst young children, it appears to be a key source of caffeine for this age group.

Table 5: Percentage contribution of key caffeine-containing foods to estimated caffeine intakes of New Zealand children<sup>^</sup> and adults<sup>#</sup>

Age group	Gender	Biscuits, cakes, muffins and pastries	Chocolate	Cocoa & chocolate drinks	Coffee	Energy drinks	Soft drinks	Tea
5 - 12 yrs <sup>^</sup>	All	11	6	7	10	2	30	32
13 - 15 yrs <sup>^</sup>	All	6	4	4	23	3	32	29
15 - 18 yrs <sup>#</sup>	Male	18	7	4	17	7	23	9
	Female	22	10	4	15	6	18	13
19 - 30 yrs <sup>#</sup>	Male	3	10	2	40	8	17	13
	Female	3	5	2	38	6	12	21
31 - 50 yrs <sup>#</sup>	Male	3	2	<1	55	3	6	26
	Female	2	3	1	56	1	5	30
51 - 70 yrs <sup>#</sup>	Male	1	2	<1	52	<1	2	42
	Female	1	2	<1	48	<1	2	44

71+ yrs <sup>#</sup>	Male	3	1	<1	38	<1	1	56
	Female	1	2	<1	38	<1	<1	58
>15 yrs <sup>#</sup>	Male	3	4	1	48	3	8	30
	Female	3	3	1	46	2	6	35
	All	3	4	1	47	3	7	32

Notes to Table 5:

Shading indicates these food groups contribute 10 percent or more to total caffeine exposure.

\* New Zealand Institute of Environmental Science and Research Limited, 2010.

^ Data based on consumers of caffeine only from the 2002 New Zealand National Children's Nutrition Survey data.

# Data based on consumers of caffeine only from the 2008/09 National Adults Nutrition Survey data modelled by the New Zealand Ministry for Primary Industries (unpublished).

Trends in National Nutrition Survey data can provide information on the changing dietary patterns of consumers and increases in caffeine intakes. However, it is difficult to determine whether the introduction of relatively new products like energy drinks and energy shots to the market has caused an overall increase in caffeine consumption, or whether one source of caffeine is being substituted for another. Public health concerns may arise where sources of nutrient dense foods such as milk may be being substituted for energy dense but nutrient poor foods, such as soft drinks.

#### 4.11 MARKETING OF CAFFEINE-CONTAINING PRODUCTS

The marketing and advertising of caffeine-containing products varies considerably depending on the caffeine source and product itself. Messaging associated with coffee often focuses on well-being, sociability, positivity and happiness. The advertising of kola-type beverages has generally been around flavour and brand 'personality', (The Coca-Cola Company, 2011) while energy drinks and some soft drinks are associated with edgier campaigns, celebrity endorsement, sponsorship of major events, with messages focusing on productivity, risk, and 'energy'. The association of major energy drink brands with extreme sports is indicative of this (Red Bull Australia Pty Limited, 2013).

The advertising of energy drinks promotes the functionality of caffeine and other ingredients for energy, performance and stimulation. The sweetening of energy drinks by sugar or sugar substitutes may assist in masking some of the intrinsic bitterness of caffeine, potentially making these products more acceptable to non-coffee or tea drinkers and less mature palates.

The role of caffeine in enhancing sports performance has led to an expansion of caffeine-containing sports foods in the market place. These products may be marketed more broadly to a range of consumers, from higher level athletes to consumers who engage more casually in sporting activities.

#### 4.12 COMMUNITY CONCERNS

Community concerns about energy drinks and energy shots have been reflected in media reports and through correspondence to Ministers in Australia and New Zealand. These concerns often relate to excessive consumption of caffeine and behavioral effects on children, the products containing caffeine in junior sport, and the mixing of energy drinks with alcohol.

## 4.13 RISKS ASSOCIATED WITH CONSUMING CAFFEINE

### 4.13.1 Risks to adults

In habitual caffeine consumers, cessation of consumption results in a withdrawal syndrome characterised by headache, fatigue, drowsiness, depression, difficulty concentrating, irritability, and lack of clarity in thinking. Caffeine increases serum homocysteine, a risk factor for cardiovascular disease, and induces bone loss in postmenopausal women (Hayes, 2008).

Caffeine intake of 0.5-1 g is considered to be the lower intake of toxic effects in humans (Hayes, 2008). The toxic effects of caffeine include vomiting, abdominal pain, and central nervous system symptoms such as agitation, altered conscious state, rigidity and seizures (Hayes, 2008). Cardiovascular effects include supraventricular and ventricular tachyarrhythmia, and the direct cause of death is often described as ventricular fibrillation (Thelander et al., 2010).

In 2000, the FSANZ Expert Working Group for Caffeine identified negative effects of caffeine at different doses, including increased anxiety levels at doses of 210 mg in adults (3 mg/kg bw/day in 70 kg adults; equivalent to consumption of approximately three cups of instant coffee); and reduced ability to sleep at doses of 100 mg (1.4 mg/kg bw/day in 70 kg adults) at bedtime (Smith et al., 2000). Negative effects of caffeine at high doses ( $\geq 500$  mg/day) were reported to include increased anxiety, impaired sleep, impaired fine motor control (which may be related to increased anxiety) and unfavourable subjective and somatic effects and performance disruption.

Negative effects associated with stimulation of the central nervous system such as dizziness, rapid heartbeat (tachycardia), irritability, and tremors are the most commonly reported adverse events seen following ingestion of caffeine at the quantities present in energy drinks and coffee. This is not limited to sensitive individuals and is at a dose of 4-6 mg/kg body mass (doses of 300-400 mg) for the average 70 kg male.

Fatalities in adults have been associated with high levels of caffeine consumption with caffeine intakes from 5 to 10 grams (Hayes, 2008). Data on caffeine-associated fatalities are available from records of forensic autopsies. Of 79,750 forensic autopsies performed in Sweden between 1992 and 2009, 830 (1 per cent) were found to have caffeine concentrations in blood exceeding 10  $\mu\text{g/g}$  (Thelander et al., 2010). Twenty cases (0.02 per cent) had concentrations of caffeine exceeding 80  $\mu\text{g/g}$ , indicated as the lethal concentration (Schulz et al., 2012). While the actual dose required to reach these levels in blood is not known, 3-10 grams by mouth is generally accepted as a fatal acute oral dose for humans. The manner of death was deemed to be suicide in 12 of these cases. Information is not provided on the type of caffeine product consumed; however, in another series of four reported fatalities from Sweden, each had a history of consuming large quantities of over-the-counter caffeine tablets (Holmgren, 2004).

The Coroner's report on the death of a New Zealand woman, who reportedly consumed up to 9 litres of Coca-Cola per day, suggested that consumption of the caffeine containing kola drink was associated with her death (Crerar, 2013). The contributing factors to fatality identified in the Coroner's Report closely relate to the known human toxicity of caffeine as stated above.

#### 4.13.2 Risks to children and adolescents

The FSANZ Expert Working Group for Caffeine reported that: caffeine increases anxiety levels in children at doses of 95 mg (3 mg/kg bw/day in children aged 5–12 years with a mean bodyweight of 32 kg; approximately two cans of cola) and caffeine use disrupts sleep patterns; and moderate to high doses of caffeine (approximately 100–400 mg) increase nervousness, jitteriness, fidgetiness, and decrease sluggishness in children and adolescents (Smith et al., 2000). Fatalities occur in children at a caffeine intake of five grams (Hayes, 2008).

A review of the evidence on the effects and overseas regulation of energy drinks, the *Review of the Evidence of the Effects and International Regulation of Caffeinated Energy Drinks (the CED Review)*, commissioned by the Department of Health and Ageing reported that similar effects of caffeine in children are also described in other reports (Department of Health and Ageing, 2011). However, it also noted some studies have been reported in which single doses of caffeine up to 10 mg/kg body mass in children had either no effect or small inconsistent effects on mood, and behavioural, cognitive and motor functions.

The *CED Review* noted that there was insufficient evidence to determine whether or not caffeine consumption established early in life can contribute to negative long-term health outcomes in children (Smith et al., 2000, cited in Department of Health and Ageing (2011)).

#### 4.13.3 Risks to pregnant women

The *CED Review* found that some authors of observational studies have concluded that caffeine intake is harmful to the foetus, causing growth restriction, reduced birth weight, preterm birth or stillbirth. These reports have led to the conclusion that reproductive-aged and pregnant women are at-risk subgroups of the population who may require specific advice on moderating their daily caffeine intake.

A 2013 Cochrane review (Jahanfar and Jaafar, 2013) into the effects of restricted caffeine intake by mothers on foetal and neonatal health and pregnancy outcome found insufficient evidence to confirm or refute the effectiveness of caffeine avoidance on birth weight or other pregnancy outcomes, including foetal hypoxia, foetal tachycardia and arrhythmias, foetal growth restriction, stillbirth and miscarriage. Findings from the Cochrane review were based on one randomised controlled trial that met the inclusion criteria.

Some countries have introduced advice for limiting caffeine use during pregnancy. The advice, depending on the country, typically suggests limiting caffeine exposure to no more than 200–300 mg per day.

#### 4.13.4 Risks relating to energy drinks

The *CED Review* found limited availability of comprehensive information, risk assessment data and peer-reviewed scientific research about consumption of caffeine in energy drinks. Several of the reviews and articles identified in the literature review report cases of overconsumption and adverse reactions, as well as alleged fatalities associated with energy drinks (Department of Health and Ageing, 2011). However, the *CED Review* found no high-quality scientific studies that clearly demonstrated a causal link between energy drink exposure and serious adverse health effects.

Although energy drink consumption does not appear to be harmful if these products are consumed within the recommended levels in the short term, there is concern about

overconsumption of these products (as with other products containing caffeine). Data from calls to poisons information centres in Australia indicate that reports of adverse reactions allegedly caused by overconsumption of energy drinks are increasing, particularly in adolescents (NSW Poisons Information Centre, Jan 2004 – Dec 2010, cited in Gunja and Brown, 2012).

**Question 5: Is there any other relevant evidence relating to the risks associated with consuming caffeine not provided here or in the listed references? If so please provide details and references.**

#### 4.13.5 Current risk management strategies

At present, risks associated with caffeine consumption are managed by restricting the addition of caffeine to kola-type beverages and FCBs and providing maximum levels for caffeine in these products in the Food Code.

In addition, the Food Code and the Supplemented Food Standard have a number of labelling requirements, including that any food or beverage that contains guarana or its extracts must include a statement on the label that the product contains caffeine. FCBs have additional requirements for advisory statements as outlined in Standard 2.6.4, as do supplemented foods sold under the Supplemented Food Standard.

Government agencies also provide advice to the public as a risk management measure. For example, the New Zealand Ministry of Health Food and Nutrition Guidelines for Healthy Children and Young People states that energy drinks or energy shots are not recommended for children or young people. It also recommends that children and young people should limit their intake of food and drinks containing caffeine (Ministry of Health, 2012).

#### 4.13.6 Positive effects of caffeine

Studies have shown caffeine consumption may improve cognitive performance. When taken at repeated low to moderate doses in the diet during the day (60-400 mg/day), caffeine has been shown to increase alertness and reduce fatigue and may improve performance on vigilance tasks and simple tasks requiring sustained response (Smith et al. 2000).

##### *Role of caffeine in sports performance*

There are a number of studies and reviews on the use of caffeine as an ergogenic aid, or to enhance performance, in sporting activities. Recent evidence indicates that caffeine supplementation at a low dose of 1-3 mg/kg body weight (around 70 – 150 mg) before or during exercise may improve sports performance in activities lasting an hour or more (Burke and Deakin, 2006). This is a change from earlier studies indicating that 6-9 mg caffeine per kg body weight had an effect (Burke and Deakin, 2006).

There is currently limited evidence of a dose-response relationship for caffeine, i.e. that sports performance increases with an increase in caffeine intake. Evidence is also limited on whether caffeine from products such as coffee and energy drinks has a similar physiological effect to that of pure caffeine supplementation (Graham, 2001).

**Question 6: Is there any other relevant evidence relating to the positive effects of caffeine not provided here or in the listed references? If so, please provide details and references**

## 5 Defining the problems associated with the Policy Guideline

The preceding sections have described the current context for the regulation of caffeine. This section defines the problems associated with the existing Ministerial Council Policy Guideline on the Addition of Caffeine to Foods.

Policy Guidelines are issued by the Legislative and Governance Forum on Food Regulation to assist FSANZ in developing or reviewing food standards. Several problems have been identified with the Ministerial Council Policy Guideline. These are outlined below.

### *Ministerial Council Policy Guideline does not meet stated objective*

The wording of the Ministerial Council Policy Guideline reflects current practice rather than providing guidance to FSANZ. In particular, the guidance to maintain the status quo ‘until further evidence becomes available’ is problematic because it is unclear as to:

- who is responsible for determining whether further evidence is available;
- what evidence would be required; or
- what guidance should apply if it is established that ‘further evidence’ is available.

There is a lack of clarity in the existing regulations in relation to the addition of caffeine to foods other than kola drinks, FCBs and formulated beverages. For example, the Food Code is silent on the addition of caffeine to formulated supplementary sports foods and electrolyte drinks. This lack of clarity suggests that new products containing caffeine may be able to be introduced without reference to policy guidance in relation to limiting the possible adverse effects of caffeine on vulnerable population groups.

The Ministerial Council Policy Guideline states that until further evidence becomes available, caffeine regulation (as currently in place in Australia and New Zealand) should maintain the status quo by:

- maintaining the current additive permissions for caffeine; and
- restricting the use of new products containing non-traditional caffeine-rich ingredients (including guarana) to boost the caffeine content in other food, beyond the current provisions for caffeine.

Having regard to the Ministerial Council policy guideline is ineffective because:

- In practice the Food Code, with few exceptions, **does not** restrict the addition of ingredients that naturally contain caffeine (guarana, tea, coffee, etc) to any food and there is therefore no upper limit on how much caffeine can be present. Guarana extract is the most common ingredient used to 'add' caffeine to foods.
- There is a lack of consistency in the application of requirements around caffeine across different food categories in the Food Code which has resulted in regulatory uncertainty.

### *Trans-Tasman harmonisation*

As the Ministerial Council Policy Guideline asks FSANZ to ‘maintain the status quo’ as currently in place in Australia, it does not provide a framework for reviewing the regulation of caffeine in Australia and New Zealand with the objective of trans-Tasman harmonisation. In New Zealand caffeine is regulated under both the Food Code and the Supplemented Food Standard. Supplemented foods can be imported into Australia from New Zealand under the provisions of the TTMRA.

The Supplemented Food Standard is an interim standard in place until appropriate provisions for supplemented foods are developed in the Food Code. The guidance to ‘maintain the status quo’ makes it difficult to undertake the risk-based development of appropriate provisions in the Food Code for supplemented foods that contain caffeine.

### *The desirability of risk-based regulation*

In seeking to maintain the status quo, the Ministerial Council Policy Guideline may have the effect of restricting new products without reference to a risk-based approach. In addition, while the intent of the Ministerial Council Policy Guideline is focused on limiting the exposure of vulnerable population groups to caffeine, the guidance itself applies to the composition of foods with added caffeine or caffeine rich ingredients. However, recent data indicates that caffeine intakes for children 5-15 years of age is derived from a combination of foods containing naturally occurring caffeine (tea, biscuits, coffee) and foods containing added caffeine (e.g. soft drinks). It is therefore unclear whether the Ministerial Council Policy Guideline contributes to the consideration of risks to all vulnerable population groups.

### *Reflecting best practice regulation principles*

The Ministerial Council Policy Guideline does not adequately reflect best practice regulation principles. For example, it does not contemplate the use of tools like education in the risk management of caffeine.

### *Taking account of overseas and international approaches*

Policy concerning the regulation of caffeine is currently under review in Europe, United States and Canada. The Ministerial Council Policy Guideline was made before these reviews, and so may not reflect current international best practice.

**Question 7: Are there any other problems that should be considered here? If so, please provide details and justification.**

## 6 Objectives

The objectives of a review of the Ministerial Council Policy Guideline underpinning the regulatory management of caffeine in the food supply in Australia and New Zealand are to:

- determine whether the Ministerial Council Policy Guideline provides an effective framework to guide a review of regulation applying to caffeine in the food supply in light of the range of products currently on the market and potential future developments;
- provide clear and unambiguous policy guidance, for example providing clarity around the treatment of caffeine-rich ingredients in food and managing risks to vulnerable population groups;
- identify opportunities to harmonise the regulation of caffeine containing foods currently regulated under the Food Code or under the New Zealand Food (Supplemented Food) Standard 2010;
- ensure that the Ministerial Council Policy Guideline is in line with the current requirements for food policy guidelines as set out in the *Principles and Protocols for the Development of Food Regulation Policy Guidelines*.

**Question 8: Are there any other objectives that should be considered here? If so, please provide details and justification.**

## 7 Statement of options

The FRSC Caffeine Working Group has identified three options in relation to the Ministerial Council Policy Guideline. These options are described below.

### **Option 1: Make no changes to the Ministerial Council Policy Guideline on the Addition of Caffeine to Foods**

This means:

- that the policy guidance to FSANZ includes recommendations to:
  - make no changes to the current additive permissions for caffeine; and
  - restrict the use of new products containing non-traditional caffeine rich ingredients to boost the caffeine content in other food, beyond the current provisions for caffeine.
- that FSANZ is also advised that:
  - foods containing naturally occurring caffeine, such as tea, coffee and cocoa are to continue to be allowed, and should not require specific labelling; and
  - Guarana, as a non-traditional food containing caffeine, should continue to have special labelling provisions, as outlined in the Food Code.

### **Option 2: Amend the Ministerial Council Policy Guideline to address the issues raised in the problem definition**

This means:

- amending the Ministerial Council Policy Guideline to remove the reference to ‘maintain the status quo’ and to remove the exclusion of tea, coffee and cocoa from scope of the Policy Guideline;
- the amended Policy Guideline would provide guidance that would assist FSANZ in undertaking a review of relevant standards if necessary with special focus on managing risks to vulnerable populations;
- changing the name of the Ministerial Council Policy Guideline to “*Policy Guideline on the Regulatory Management of Caffeine in the Food Supply*”.

An example of a draft Policy Guideline based on this option is provided in [chapter 9](#).

### **Option 3: Rescind the Ministerial Council Policy Guideline**

This means:

- there would be no Policy Guideline;
- any review of the standards relating to caffeine undertaken by FSANZ would be in the absence of specific policy guidance (but would still conform to the objectives of the FSANZ Act, including, most importantly, the protection of public health and safety).

**Question 9: Are there any other feasible options in relation to the Ministerial Council Policy Guideline on the Addition of Caffeine to Foods which have not been listed here? If so, please provide details and justification.**

## 8 Analysis of options

A Policy Guideline only has a regulatory impact if it informs the development or review by FSANZ of regulatory standards. Policy Guidelines are not directions to FSANZ, but they may impact on the scope of FSANZ’s work, or the range of issues FSANZ considers in undertaking standards development or review. This makes anticipating the effects of a change to a Policy Guideline difficult.

For the purposes of analysis, this section assumes that should current information or evidence be sufficient to cause the Forum to request FSANZ to conduct a review of that evidence, and the consequential review of the Food Code that may be appropriate, that FSANZ would undertake a review of the regulatory standards applying to caffeine in the Food Code based on the form of Policy Guideline (or lack of Policy Guideline) described in each option.

It should be emphasised that any decision on the future of the Ministerial Council Policy Guideline does not necessarily trigger a review of the standards by FSANZ. This decision would need to be made by the Forum or by FSANZ. FSANZ also has the discretion to define the scope of its reviews, and so while FSANZ is obliged to ‘have regard’ to a Policy Guideline it can consider a wider range of matters, and reach different conclusion if warranted by evidence and consistent with its objectives (in section 18 of the FSANZ Act 1991).

### 8.1 OPTION 1: MAKE NO CHANGES TO THE MINISTERIAL COUNCIL POLICY GUIDELINE ON THE ADDITION OF CAFFEINE TO FOODS

FRSC would recommend to the Forum that no action is taken to amend the Ministerial Council Policy Guideline.

The Ministerial Council Policy Guideline (refer Appendix 2) suggests that current additive permissions for caffeine should be maintained and that the use of new products containing non-traditional caffeine-rich ingredients should be restricted until further evidence becomes available.

The impacts of a review of standards related to caffeine based on the Ministerial Council Policy Guideline are outlined below.

Stakeholder group	Advantages	Disadvantages
Consumers	No particular advantages.	Limits the use of labelling as a risk management tool for products with added caffeine and non-traditional foods with naturally occurring caffeine, even though traditional foods with naturally occurring caffeine (e.g. tea, coffee and cocoa) are key dietary sources of caffeine. There could be an impact on consumer choice of products containing new ingredients with naturally occurring caffeine. This is because the Ministerial Council Policy Guideline suggests restrictions should be applied on such new ingredients. However, this suggestion is not based on a risk assessment.

Stakeholder group	Advantages	Disadvantages
Industry	Signals to industry government expectations in relation to specific risk management tools in relation to the regulatory management of caffeine (e.g. labelling of foods containing added caffeine, restrictions on new ingredients containing naturally occurring caffeine).	May lead to less scope for innovation, as non risk-based restrictions may be placed on use of new ingredients containing naturally occurring caffeine. Not equitable across industry sectors, because some of the primary dietary sources of caffeine (e.g. tea, coffee and cocoa) are not included in scope of the full range of risk management tools (e.g. labelling). This is because the Ministerial Council Policy Guideline excludes the full range of risk management tools.
Government	No particular advantages.	Inconsistent with general approach to food safety regulation as it is not risk-based, particularly as primary sources of dietary exposure to caffeine are excluded in the full range of management tools in the Ministerial Council Policy Guideline. Intends to communicate government policy, but lack of clarity in the Ministerial Council Policy Guideline means it is not clear it can contribute to realisation of that policy.

## 8.2 OPTION 2: AMEND THE MINISTERIAL COUNCIL POLICY GUIDELINE TO ADDRESS THE ISSUES RAISED IN THE PROBLEM DEFINITION

This option is to amend the Ministerial Council Policy Guideline to address the issues raised in the ‘case for reviewing the Policy Guideline’ and change the name to “*Policy Guideline on the Regulatory Management of Caffeine in the Food Supply*”.

The scope of the Ministerial Council Policy Guideline would include foods and ingredients with both naturally occurring and added caffeine, as well as possible future uses for caffeine in food. It would focus on managing the risks to vulnerable population groups. A draft version of the Policy Guideline proposed under this option is provided in [chapter 9](#) of this paper.

The potential impacts of a review of standards related to caffeine, based on a draft Policy Guideline as set out in [chapter 9](#) of this paper, are outlined below.

Stakeholder group	Advantages	Disadvantages
Consumers	Provides for a risk based review while focusing on vulnerable populations and including all dietary sources of caffeine within scope for the full range of risk management tools.	Lack of visibility in Policy Guideline of specific risk management tools (e.g. labelling and certain restrictions) may impact consumer confidence in regulatory management of caffeine.

Stakeholder group	Advantages	Disadvantages
Industry	Equal treatment of all industry sectors within a risk a management framework. Potential scope for product innovation within a risk management framework, paying particular attention to vulnerable population groups.	Those industry sectors formerly excluded from scope may face regulatory changes (if recommended for risk management purposes).
Government	Wider scope and consistency with risk management principles means the policy aligns with food regulation policy more generally. May provide greater scope for trans Tasman harmonisation.	Depending on whether the Ministerial Council Policy Guideline is reviewed, maintained or rescinded there is the potential for change to impact on government agencies.

### 8.3 OPTION 3: RESCIND THE MINISTERIAL COUNCIL POLICY GUIDELINE

If FSANZ were to review the standards relating to caffeine under this option (i.e. without a Policy Guideline) it would do so on the basis of the objectives outlined in the FSANZ Act 1991 and the latest available evidence.

The potential impacts of a review of standards relating to caffeine in the absence of a Policy Guideline are set out below.

Stakeholder group	Advantages	Disadvantages
Consumers	Scope of the review entirely up to FSANZ and so is likely to correspond with risk management principles.	Lack of Policy Guideline and visibility about specific risk management tools and vulnerable population groups may affect confidence in regulatory management of caffeine.
Industry	Scope of any review entirely up to FSANZ and so likely to correspond with risk management principles, and equal treatment of industry sectors.	Those industry sectors formerly excluded from scope of full range of risk management tools (e.g. labelling) may face regulatory changes (if recommended for risk management purposes).
Government	Wider scope and consistency with risk management principles means consistency with approaches to food regulation policy more generally. May provide greater scope for trans-Tasman harmonisation.	Other than statutory requirements, FSANZ would not have clear guidance from Ministers for a review. Lack of policy guideline means it may be more challenging to communicate governments' focus on risk management, especially for vulnerable population groups.

**Question 10: Are there any impacts (advantages or disadvantages) on consumers, industry or government which have not been considered here? If so, please provide details (noting the impacts assume that a review of regulatory standards would have reference to the Policy Guideline described in the options).**

**Question 11: Can you provide data to support the potential costs and/or benefits of impacts of policy options? If so, please provide details.**

**Question 12: Please indicate your preferred option (as stated or otherwise) and provide details as to why you consider this option suitable.**

## 9 Draft Policy Guideline

Based on the options analysis, the FRSC Working Group has identified that the preferred approach is option 2: to amend the Ministerial Council Policy Guideline in a way that more readily allows for review of the current regulation of caffeine in the food supply. This would involve removing the 'Other principles' and 'Policy guidance' sections and replace these with specific principles to assist FSANZ in undertaking a review of standards relating to caffeine, as necessary, with special focus on managing risks to vulnerable populations.

### **Legislative and governance forum on food regulation**

#### ***Regulation of Caffeine in Foods***

##### *Scope/aim*

This Policy Guideline provides guidance on the expectations of the Legislative and Governance Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council) for the regulation of caffeine in foods.

##### *High order policy principles*

The Food Standards Australia New Zealand Act (FSANZ) 1991 establishes a number of objectives for FSANZ in developing or reviewing of food standards (section 18 of the FSANZ Act).

The FSANZ Act states that the objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:

- (a) the protection of public health and safety; and
- (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
- (c) the prevention of misleading or deceptive conduct.

The FSANZ Act states that in developing or reviewing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:

- (a) the need for standards to be based on risk analysis using the best available scientific evidence;
- (b) the promotion of consistency between domestic and international food standards;
- (c) the desirability of an efficient and internationally competitive food industry;
- (d) the promotion of fair trading in food;
- (e) any written policy guidelines formulated by the Australian and New Zealand Food Regulation Ministerial Council (that was established by the Food Regulations Agreement in 2000).

These objectives apply to the development of standards regulating the use of caffeine in foods.

A number of other policies are also relevant to the development of food standards including:

- the Council Of Australian Governments document 'Principles and Guidelines for National Standard Setting and Regulatory Action by Australia and New Zealand Food;
- Regulatory Ministerial Council and Standard Setting Bodies' (1995, amended 1997) (Australia only);
- New Zealand Code of Good Regulatory Practice (November 1997);
- the Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System;
- relevant World Health Organization agreements; and
- relevant World Trade Organization agreements, standards and guidelines.

#### *Specific policy principles*

The regulatory management of caffeine in the food supply should:

- (a) manage risks to vulnerable population groups such as children, adolescents, pregnant women and caffeine sensitive consumers
- (b) be informed by ongoing monitoring of emerging evidence and the regulation of caffeine in overseas jurisdictions
- (c) consider exposure to caffeine across the food supply.

#### *Additional policy guidance*

Where possible, FSANZ is encouraged to work with health research agencies to monitor caffeine consumption across the population, and particularly consumption by children.

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# 11 Appendix 1: Food Regulation Policy Options Paper – Regulation of Caffeine in Foods - Submitters Response Form

## Invitation for Submissions

The Food Regulation Standing Committee (FRSC) invites public comment on this Food Regulation Policy Options Paper for the purpose of formulating policy guidelines in relation to the regulation of caffeine in the Australian and New Zealand food supplies.

The purpose of the consultation paper is to establish if the Ministerial Council Policy Guideline needs to be updated, maintained or rescinded in order to provide Food Standards Australia New Zealand (FSANZ) with appropriate guidance to assist in the development or review of food standards relating to caffeine in ‘food’.

While this paper discusses the standards that currently regulate the addition of caffeine in food in Australia and New Zealand, the options presented relate only to the Ministerial Council Policy Guideline and not to the standards themselves. It should be emphasised that any decision on the future of the Ministerial Council Policy Guideline does not necessarily trigger a review of the standards by FSANZ. The regulatory standards for caffeine are outside the scope of this review. The issue of mixing alcohol with energy drinks is also outside the scope of this review and is being investigated separately by the Intergovernmental Committee on Drugs and FRSC.

Submissions must be made in writing and should clearly be marked with the word ‘Submission’ and ‘Caffeine Options Paper’. While the Food Regulation Secretariat in Australia and the Ministry for Primary Industries in New Zealand accepts submissions in hard copy, **it is preferable to receive submissions electronically** by emailing your submission directly to [foodregulationsecretariat@health.gov.au](mailto:foodregulationsecretariat@health.gov.au) in Australia, or [Caffeine.Review@mpi.govt.nz](mailto:Caffeine.Review@mpi.govt.nz) in New Zealand.

There is no need to send a hard copy of your submission if you have submitted it by email. We will endeavour to formally acknowledge receipt of submissions within five business days, of the closing date for submissions.

**Question 1: Can you provide any evidence about the level of compliance with and/or effectiveness of these industry codes? (Refer [chapter 4.4](#))**

**Question 2: Are there any international regulations of relevance that have not been provided here or in Appendix 3? If so, please provide references. (Refer [chapter 4.5](#))**

**Question 3: Are there any other relevant data not provided here? If so, please provide details and references. (Refer [chapter 4.7](#))**

**Question 4:** Can you provide any additional information about the use of caffeine as an ingredient in foods and/or the formulation of products using caffeine or caffeine containing ingredients. If so, please provide details. (Refer [chapter 4.9](#))

**Question 5:** Is there any other relevant evidence relating to the risks associated with consuming caffeine not provided here or in the listed references? If so please provide details and references. (Refer [chapter 4.13.4](#))

**Question 6:** Is there any other relevant evidence relating to the positive effects of caffeine not provided here or in the listed references? If so, please provide details and references. (Refer [chapter 4.13.6](#))

**Question 7:** Are there any other problems that should be considered here? If so, please provide details and justification. (Refer [chapter 5](#))

**Question 8:** Are there any other objectives that should be considered here? If so, please provide details and justification. (Refer [chapter 6](#))

**Question 9:** Are there any other feasible options in relation to the Ministerial Council Policy Guideline on the Addition of Caffeine to Foods which have not been listed here? If so, please provide details and justification. (Refer [chapter 7](#))

**Question 10:** Are there any impacts (advantages or disadvantages) on consumers, industry or government which have not been considered here? If so, please provide details (noting the impacts assume that a review of regulatory standards would have reference to the Policy Guideline described in the options). (Refer [chapter 8.3](#))

**Question 11:** Can you provide data to support the potential costs and/or benefits of impacts of policy options? If so, please provide details. (Refer [chapter 8.3](#))

**Question 12:** Please indicate your preferred option (as stated or otherwise) and provide details as to why you consider this option suitable. (Refer [chapter 8.3](#))

## 12 Appendix 2: Ministerial Council Policy Guideline on the Addition of Caffeine to Foods 2003

### *Ministerial Council Policy Guideline on the Addition of Caffeine to Foods*

Endorsed by the Ministerial Council on 4 April 2003

#### *Scope/Aim*

To limit the exposure of vulnerable individuals to foods containing caffeine.

#### *High Order Principles*

- (1) Give priority to protecting public health and safety.
- (2) Ensure that consumers have access to sufficient information to enable informed and healthy food choices.
- (3) Ensure that industry innovation and competitiveness is supported, except where public health and safety is affected.
- (4) Be consistent with, and complement, Australia and New Zealand national policies and legislation including those relating to nutrition and health promotion, fair trading, industry growth and international trade and innovation.
- (5) Be cost-effective overall, not more trade restrictive than necessary, and comply with Australia's and New Zealand's obligations under the WTO Agreements.

#### *Other Principles*

- (1) Endeavour to limit the possible adverse effect of caffeine containing foods on vulnerable sub-groups of the population.
- (2) Ensure that the effect of caffeine additions to individual foods is considered in the context of the total diet.
- (3) Ensure the appropriate use of advisory statements on caffeine-containing foods in alignment with scientifically substantiated risk to vulnerable sub-groups of the population.

#### *Policy Guidance*

Until further evidence becomes available, maintain the status quo (as currently in place in Australia) for caffeine regulation by:

- Maintaining the current additive permissions for caffeine; and
- Restricting the use of new products containing non-traditional caffeine-rich ingredients (including guarana) to boost the caffeine content in other food, beyond the current provisions for caffeine.

Caffeinated kola drinks and formulated caffeinated beverages will be permitted in accordance with the current standards.

Foods, which naturally contain caffeine and have a long history of use and consumer awareness/association with caffeine, such as tea, coffee and cocoa, are to be exempt from the labelling provisions and the use of these foods naturally containing caffeine to be added to other foods will continue to be allowed. Guarana, as a non-traditional food containing caffeine, will continue to have special labelling provisions outlined in the Food Code.

## 13 Appendix 3: Overseas regulation

### *Overseas regulation - caffeine*

#### *European Union*

In the European Union the use of caffeine as flavouring in foods has to be clearly indicated on the label. Commission Directive 2002/67/EC provides for consumers to be given clear and precise information on the presence of caffeine in a foodstuff. Caffeine must be mentioned by name in the list of ingredients immediately after the term ‘flavouring’.

Beverages that contain a proportion of more than 150 mg of caffeine per litre must be labelled ‘High caffeine content’, followed by the quantity of caffeine expressed in milligrams per 100mL. This wording must appear in the same field of vision as the name of the drink. These labelling requirements do not apply to products sold as ‘tea’ and ‘coffee’.

#### *United States*

In the United States, additives such as caffeine, whether added to a conventional food or as an ingredient in a dietary supplement, must be used in accordance with food additive regulation which specifies the conditions under which it must be used. However, such regulation is not needed if the substance is ‘generally recognised as safe’ (GRAS) (i.e. substances generally recognised to be safe by qualified experts). The FDA Code of Federal Regulations, nr 21CFR182.1180, states that caffeine is GRAS when used in cold drinks such as cola-based beverages and that the level of caffeine in these types of beverages must not exceed 0.02 per cent (i.e. 200ppm).

Caffeine may also be used as an ingredient in other conventional foods or dietary supplements provided the manufacturer can assure it is safe under the conditions of use that they specify in the labelling. GRAS substances, and dietary supplements, are not required to undergo pre-market assessment.

Any food product that contains caffeine must list caffeine as an ingredient on the product label. However, the actual quantity of caffeine contained in the product does not have to be stated on the label and there are no further labelling requirements.

#### *Canada*

In Canada, cola-type beverages have historically been the only food products allowed to contain caffeine, as a food additive to characterise the nature of cola-type beverages and to a maximum of 200ppm. However, in response to a submission to allow caffeine and caffeine citrate in non-alcoholic carbonated water-based flavoured beverages and sweetened beverages other than cola type drinks, an Interim Marketing Authorization has been granted to allow such use up to a level of 150ppm caffeine.

In current Canadian legislation, caffeine does not have to be listed as an ingredient on the label of food products unless it has been added separately to the product as a pure substance. With caffeine that has been added to a food product as an additive, such as with cola-type beverages, there is no requirement to quantitatively state the amount of caffeine present in the product. For natural sources of caffeine such as guarana, the food label is not required to identify the presence of caffeine nor state the amount of caffeine that the product contains.

However in 2010, the Canadian government published draft voluntary guidance for the labelling of pre-packaged foods containing caffeine which suggests considerably more detail.

### *Overseas regulation – Energy drinks*

Regulation of energy drinks varies considerably around the globe and is in differing stages of development.

#### *European Union*

In the European Union, there is a requirement to label energy drinks on the basis of informing consumers about high levels of caffeine present in foods and soft drinks that would not normally contain caffeine. A beverage that contains caffeine in excess of 150 mg/L must place the following message on its label directly under where the product name is stated: 'High caffeine content'. This message must then be followed in brackets by the caffeine content expressed in mg/100 mL.

The caffeine level of 150 mg/L is used in the EU as the regulatory differentiator between energy drinks and other beverages. For other beverages caffeine is permitted as a flavouring agent up to 150 mg/L. When used in this way, caffeine must be mentioned by name in the list of ingredients immediately after the word 'flavouring'. There is, however, no requirement for quantification of the caffeine present in the foodstuff.

Energy shots are addressed separately in the EU through Commission Directive 2002/46/EC, which governs food supplements. Under this Directive, food supplements may contain a wide range of nutrients and other ingredients including vitamins, minerals, various plants and herbal extracts. Whilst caffeine cannot be added in its chemical form, guarana and other herbal sources of caffeine could be included. There are specific labelling requirements, including the names and quantities of substances (including quantity per portion), which characterise: the product; daily recommended doses and warnings against exceeding that dose; and that the products should be stored out of the reach of children. This Directive notes that specific rules regarding other substances with nutritional or physiological effects should be laid down at a later stage.

Meanwhile, EU member states can institute their own national legislation where they consider it is in the public health and safety interests of their population. With regard to energy drinks this has been exemplified by the setting of upper caffeine levels (e.g. Denmark and France), reported 'banning' of energy drinks, or additional labelling requirements (e.g. Finland).

In February 2013, the European Commission made a request to EFSA to conduct a scientific opinion on the safety of caffeine. Concern was raised by several Member States that consumption of caffeine may be encouraged following the favourable evaluation of caffeine-related health claims on sports performance. The European Commission has therefore asked EFSA to 'review the available data with a view to determining intake levels which would pose no safety concern for the main population sub-groups'. The work requested is an extensive literature search and review as part of a safety assessment for caffeine. It is proposed that this work will commence in March 2013 and take a period of six months. The deadline for completion of the scientific opinion has not yet been determined (European Food Safety Authority, 2013).

## *Canada*

In October 2011, Health Canada published their proposed approach to managing energy drinks. The proposed Canadian policy approach is based on a fundamental change to regulating energy drinks as foods (beverages), rather than as Natural Health Products as is currently the case (Health Canada, 2011).

Under the proposed approach, minimum and maximum limits for caffeine from all sources (i.e. natural and synthetic sources) would be set, and limitations around other ingredients. Maximum levels of caffeine would be based not only on a concentration basis (ie 400 mg per litre) but also based on serve size. A single serve is defined as any energy drink container equal to or less than 591 mL, or if greater, any energy drink container that cannot be resealed. A single serve container may not exceed 180 mg caffeine per container.

In addition, energy drinks would be subject to all food-related labelling requirements, plus total caffeine will need to be declared, along with advisory statements regarding energy drinks' 'high caffeine' nature, unsuitability for various population sub-groups, and advice against mixing with alcohol.

In response to stakeholder consultation conducted during October and November 2011, Health Canada has confirmed their approach in terms of maximum limits of caffeine for single and multi-serves of serves of energy drinks. Health Canada is in the process of finalising their approach and yet to implement change to food regulation. (Health Canada, 2013).

## *Other countries*

Regulations for energy drinks in other countries are quite varied and include:

- limits on claims that can be made on the label (e.g. Japan, which limits claims if energy drinks are marketed as foods but not if they have been assessed and categorised as Foods for Specified Health Uses);
- labelling requirements that specify the quantity of caffeine per serving size and per 100 mL (e.g. South Africa); and
- health warning labels or advisory warning statements regarding the unsuitability of the product for particular population groups (e.g. South Africa, United Arab Emirates, and India).

## *References*

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