



1 November 2019

[101–19]

## Call for submissions – Urgent Proposal P1054

Pure and highly concentrated caffeine products

### INITIAL CONSIDERATION REPORT

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FSANZ is considering an urgent Proposal to prohibit the retail sale of pure and highly concentrated caffeine food products and has prepared a draft food regulatory measure. Pursuant to section 96 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist its consideration of that draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 14 November 2019**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

Hard copy submissions may be sent to one of the following addresses:

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## Executive summary

Proposal P1054 is a proposal to amend the Australia New Zealand Food Standards Code (the Code) to prohibit the retail sale of pure and highly concentrated caffeine food products.

The Code prevents caffeine's addition to or use in food only in specific circumstances or for specific purposes. The Code expressly permits caffeine for use in cola type drinks and in formulated caffeinated beverages. However, the Code does not expressly permit, prohibit or seek to regulate the retail sale of pure and highly concentrated caffeine food products more generally.

FSANZ prepared this Proposal on 20 September 2019 after reviewing and reporting to Australian Government Ministers on the current availability and regulation of caffeine, and on options for strengthening regulations and consumer warnings in relation to pure and highly concentrated caffeine food products. FSANZ's report to Ministers made 5 recommendations based on the preliminary assessment detailed in that report. The first recommendation was that FSANZ "develop and declare as urgent a proposal to amend the Code to prohibit the retail sale of pure and highly concentrated caffeine food products." This recommendation was based on FSANZ's preliminary assessment that such products pose an unacceptably high risk for consumers and as such, there was a need to act to protect public health and safety.

On the basis of that preliminary assessment, FSANZ declared this Proposal to be an urgent proposal for the purposes of Division 4 of Part 3 of the *Food Standards Australia New Zealand Act 1991* (Cth) (the FSANZ Act). Following that declaration of urgency, FSANZ undertook an initial consideration of the Proposal. This included consideration of the risks posed by pure and high caffeinated food products and of the options available to address or mitigate any such risks.

FSANZ's risk assessment confirmed its preliminary assessment that there is an immediate and acute risk posed by the sale of pure or highly purified forms of caffeine to consumers. Ingestion of small amounts of these substances can result in severe health effects, including death.

For the reasons outlined in this report, FSANZ considered the most appropriate response to that risk was to prepare a draft variation to prohibit the retail sale of foods in which total caffeine is present in a concentration of 5% (5 g/100 g) or more, in the product presented at retail sale, unless that sale or presence was expressly permitted by the Code. The continued use of caffeine as an ingredient in foods such as formulated caffeinated beverages and cola beverages are unaffected and the current lower maximum limits in the Code remain in place for those foods<sup>1</sup>. FSANZ therefore prepared a draft variation to Standard 1.1.1 of the Code for this purpose.

FSANZ seeks public submissions on its initial consideration of the Proposal (as summarised in this report) and on the proposed draft variation. FSANZ particularly seeks feedback on the proposed maximum limit for all foods of a 5% concentration and on whether stakeholders consider this limit is likely to have any unintended consequences. Submissions received will inform FSANZ's decision whether to reject, amend or approve the proposed draft variation.

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<sup>1</sup> the prohibition will operate subject to the Code's other provisions, including existing and future express permissions for caffeine in the Code and any limits or conditions imposed by and for those permissions.

# 1 Introduction

## 1.1 The Proposal

This Proposal was prepared following a review by Food Standards Australia New Zealand (FSANZ) of the safety of pure and highly concentrated caffeine food products, including current regulations and permissions for use, and of the options available for strengthening regulations and consumer warnings.

This review was undertaken at the request of the Minister for Aged Care and Senior Australians, Senator the Hon Richard Colbeck; and the Minister for Health, the Hon Greg Hunt. The Ministers' request was in response to the death of a young man in New South Wales attributed to acute caffeine toxicity associated with the consumption of a caffeine powder.

In undertaking the review, FSANZ established a Working Group including food regulatory authorities from Australia and New Zealand. The Working Group agreed the availability of pure and highly concentrated caffeine food products for retail sale posed an unacceptably high risk and should be considered urgently and separately to other products containing caffeine. FSANZ's preliminary assessment was also that such products posed an unacceptably high risk for consumers and, as such, there was a need to act to protect public health and safety.

FSANZ provided a report<sup>2</sup> to Ministers on 30 August 2019 detailing the findings of its review and making five recommendations, the first of which was that FSANZ develop and declare as urgent a proposal to amend the Code to prohibit the retail sale of pure and highly concentrated caffeine food products.

Minister Colbeck, as the responsible Australian Government Minister, publically endorsed FSANZ's findings and recommendations.

## 1.2 The current standards

The regulatory regime governing caffeine is detailed in FSANZ's report to Ministers. The following is a summary of the relevant Australia New Zealand Food Standards Code (the Code) provisions.

Australian and New Zealand food laws require food for sale in Australia to comply with any relevant requirement set by the Code. Table 1 summarises the provisions or requirements of the Code related or applicable to caffeine.

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<sup>2</sup> ['pure and highly concentrated caffeine products' report](#) and [media release](#).

**Table 1 Code provisions for caffeine permission in food**

Product	Current risk management/amount in food
<b>Any food containing caffeine as an ingredient</b>	> A Code requirement to declare added caffeine in the ingredient list.
<b>Formulated caffeinated beverages (energy drinks)</b>	> The Code restricts the amount of caffeine (maximum of 320 mg per litre). > Mandatory labelling advisory statements that the food contains caffeine and is not recommended for children (no defined age), pregnant or lactating women and individuals sensitive to caffeine. > Labels must also declare the maximum number of serves per day (based on content of certain nutrients rather than caffeine).
<b>Formulated supplementary sports foods (e.g. pre-workout supplements, protein powders)</b>	> May be regulated as either a food or a therapeutic good depending on whether it meets the definition of a food in the FSANZ Act, or the definition of a therapeutic good in the <i>Therapeutic Goods Act 1989</i> . > No express permissions for caffeine in formulated supplementary sports foods in the Code. > Standard 2.9.4 currently under review in Proposal 1010 – caffeine and labelling to be considered as part of this.
<b>Cola type drinks</b>	> The Code restricts the amount of caffeine (total caffeine must not exceed 145 mg/kg). > Labelling advisory statement 'contains caffeine'.
<b>Food containing guarana or extracts of guarana</b>	> Labelling advisory statement 'contains caffeine'

In summary –

- The Code itself does not expressly prohibit addition or use of caffeine in food. Nor does the Code itself expressly prohibit the sale of pure or highly concentrated caffeine.
- To the extent that pure and highly concentrated caffeine food products are novel foods for the purposes of the Code, their retail sale as a food and presence of caffeine as an ingredient or component in a food for retail sale would be prohibited by the Code and State and Territory food laws. The status of pure and highly concentrated caffeine food products as a novel food remains untested by food regulators and the courts.
- The Code imposes prohibitions on the use of substances as food additives, processing aids and nutritive substances, unless expressly permitted. These prohibitions apply only to substances that fall within the Code's definition of what constitutes a food additive, a processing aid or a nutritive substance for the purposes of these prohibitions.
- These prohibitions prevent the addition or use of caffeine in food in specific circumstances or for specific purposes. That is:
  - caffeine that meets the test of what constitutes 'a food additive' (as defined) cannot be used in food other than in cola type drinks;
  - nor can caffeine be used in food as 'a processing aid' (as defined) or as 'a nutritive substance' (as defined) (noting that caffeine is unlikely to be used in this manner).

- There is no express requirement in the Code that prohibits caffeine's use in or addition to food for purposes other than as 'a food additive', 'a processing aid' or 'a nutritive substance'.
- The Code expressly permits caffeine for use in cola type drinks (if used as a food additive – as defined) and in formulated caffeinated beverages. In both cases, this use is subject to compositional and labelling requirements.

### 1.3 Food Imported into Australia

Foods imported into Australia are subject to requirements under the *Imported Food Control Act 1992* (IFC Act) for compliance with Australian food standards and the requirements of public health and safety. Under the IFC Act, importers are legally responsible for ensuring the foods they import comply with the standards that apply to their products and do not pose a risk to human health.

The IFC Act provides for the Department of Agriculture to administer the Imported Food Inspection Scheme (IFIS). The *Imported Food Control Regulations 2019* sets out how the IFIS operates including the rates that foods are referred for inspection. For the operation of the IFIS, foods are either classified as a risk food and are scheduled in the *Imported Food Control Order 2019* or are a surveillance food.

Orders to classify food are made by the Minister based on risk advice from FSANZ. Food may be classified as a risk food if FSANZ advises that the food has the potential to pose a medium to high risk to public health.

#### 1.3.1 Management of caffeine products under IFIS

The Department of Agriculture considers four standards in relation to food that is likely to contain caffeine:

- Standard 2.6.2 Non-alcoholic beverages and brewed soft drinks
- Standard 2.6.4 Formulated caffeinated beverages
- Standard 2.9.3 Formulated meal replacements and formulated supplementary foods
- Standard 2.9.4 Formulated supplementary sports foods.

Foods under these standards are currently surveillance foods and are inspected for compliance via product presentation and labelling checks against relevant standards in Chapter 1 and Chapter 2 of the Code.

#### 1.3.2 Imported pure and highly concentrated caffeine food products

The Department of Agriculture targets imported food by applying profiles in the Integrated Cargo System to food tariffs. Data shows that pure caffeine is imported under the Chapter 29 – Organic Chemical tariff for 'Caffeine and its salts'. Currently, the department does not profile tariffs in Chapter 29 for inspection under the IFIS but could target products to enforce any future requirements in the Code, provided the substances were imported as food or food ingredients.

### 1.4 Food Imported into Australia from New Zealand

The Trans-Tasman Mutual Recognition Arrangement provides that food may be imported into Australia from New Zealand and sold in Australia provided it complies with the New Zealand food law. It is also exempt from inspection under the Imported Food Control Act.

### 1.4.1 New Zealand Supplemented Food Standard 2016

New Zealand food law includes the *New Zealand Supplemented Food Standard 2016*.

Clause 1.9 of the *New Zealand Food (Supplemented Food) Standard 2016*, permits caffeine to be *added* to a supplemented food for any purpose other than as a food additive, so long as the label includes: (a) an advisory statement to the effect that the food contains caffeine and is not recommended for children, pregnant or lactating women, or individuals sensitive to caffeine; and (b) the average quantity of caffeine per serve and the average quantity of caffeine per 100 mL or 100 g. There are no prescribed maximum permitted levels for caffeine under the *New Zealand Food (Supplemented Food) Standard 2016*.

There is also a general requirement around safe daily consumption which could apply to a supplemented food containing caffeine (or any other substances). This requires that a label of the supplemented food must specify an appropriate daily amount and include an advisory statement to the effect that exceeding that daily consumption may cause harm.

## 1.5 International approaches – caffeine in or as a food

The following provides an overview of the regulation of caffeine for sale to consumers in the United States of America (USA), Canada and the European Union. There is no consistent approach to regulation across the countries as outlined in Table 2 below. Further detail is provided in Appendix A.

**Table 2: International regulation of caffeine**

	Pure and highly concentrated caffeine	Foods with added caffeine	Foods with natural caffeine
<b>USA</b>	Some products consisting of only or primarily pure or highly concentrated caffeine considered to be adulterated and hence sale prohibited.	Caffeine may be used as an ingredient in foods provided it has been determined as Generally Recognised as Safe. No labelling requirements specifically for caffeine.	No compositional limits or labelling requirements specifically for caffeine.
<b>Canada</b>	Permitted for retail sale. Regulated as licensed natural health products. Labelling requirements include recommended dose and duration of use and risk information (generic requirement).	Addition of caffeine regulated as a food additive. Permitted in some beverages up to specified limits. Specific labelling requirements for caffeinated energy drinks.	No compositional limits or regulatory requirement to identify the presence of or amount of caffeine for natural sources.
<b>European Union</b>	European Commission directive does not include compositional limits but EU member states may develop these. Labelling requirements for recommended daily consumption.	Use of caffeine as a flavouring substance in food is subject to restrictions of use in certain food categories. No compositional rules if added for a nutritional or physiological effect. Specific warnings required for caffeine. The actual caffeine content must also be on the label.	Specific warnings required for some foods, excluding beverages based on coffee, tea or coffee or tea extract where the name of the food includes the term 'coffee' or 'tea'.
<b>Australia and New Zealand</b>	Food Standards Code does not expressly prohibit the sale of pure or highly concentrated caffeine.	The Code does not expressly prohibit addition or use of caffeine. Caffeine is in effect prohibited for certain categories of foods. Caffeine expressly permitted up to maximum levels	No compositional limits in the Code. 'Contains caffeine' labelling statement required for foods containing guarana.

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<p>In New Zealand, the <i>New Zealand Food (Supplemented Food) Standard 2016</i> permits caffeine to be added to a supplemented food for any purpose other than as a food additive. Supplemented foods permitted by that Standard may be imported into and sold in Australia provided under the Trans-Tasman Mutual Recognition Arrangement.</p>	<p>in cola type drinks and formulated caffeinated beverages (FCBs). 'Contains caffeine' required for these foods. Advisory statements and quantitative declaration of caffeine for FCBs.</p>
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## 1.6 Other issues: food-medicine interface

The regulation of caffeine in Australia is also complicated in that caffeine falls within what is known as 'the food-medicine interface'. Generally a product that is swallowed will be regulated either as a therapeutic good or a food. Often, claims made about a product or the appearance of the product may suggest that it is a therapeutic good. However, the fact that certain claims are made about a product does not automatically make it a therapeutic good. Nor does the fact that the product comes in capsules or powders, or is labelled as a 'dietary supplement'.

The potential regulatory overlap between certain foods and medicines at the 'food-medicine interface' means that regulators, manufacturers and importers all need a way to work out whether the Therapeutic Goods Act 1989 (TGA Act) or state or territory food legislation covers particular products. This is determined on a product by product basis via the food-medicine interface tool administered by the Therapeutic Goods Administration (TGA).

Due to this complexity, FSANZ and the TGA agreed that a two-pronged approach, managing caffeine as both a food via the Code and as a therapeutic via the TGA Act will best mitigate the potential risks. This approach is considered most pragmatic to manage acute toxicity risks, while further work is undertaken to determine if one legislative approach can be exclusively relied on.

### 1.6.1 Action taken by the Therapeutic Goods Administration

Following the recent Ministerial request and subsequent report, the TGA amended the Therapeutic Goods (Permissible Ingredients) Determination to specify that listed medicines which are undivided preparations (such as bulk powders) must not contain a concentration of caffeine greater than 1% (after March 2021) and divided preparations (such as tablets and capsules) must not contain a concentration of caffeine greater than 33%. As a result, there are currently no (and cannot be) pure-caffeine listed medicines on the Australian Register of Therapeutic Goods (ARTG). Only therapeutic goods entered in the ARTG can be lawfully supplied in Australia.

In addition, the TGA has publically consulted on a [proposal to include caffeine in Schedule 4 and 6 of the Poisons Standard](#).

Schedule 6<sup>3</sup> poisons are substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label and apply to the retail storage of poisons.

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<sup>3</sup> <https://www.tga.gov.au/publication/national-guideline-retail-storage-schedule-6-and-schedule-7-poisons>



Schedule 6 poisons also have a moderate to high toxicity which can cause death or severe injury if inhaled, taken internally or when contacts the skin or eyes. As such, this schedule has no specific relevance to foods containing caffeine for retail sale.

The proposal is on the agenda for discussion at the next Joint Advisory Committee on Medicines and Chemicals Scheduling. Under the [nominated timeframes](#) for this meeting, the earliest time a decision on this application would be implemented is 1 June 2020. If caffeine were to be included in Schedule 6, additional packaging, storage and labelling requirements would be imposed on all applicable products.

Advice to FSANZ is that exemptions in the Poisons Standard mean that any restrictions imposed as a result of that listing can only apply to the following foods:

- Food additives that contain or comprise the listed preparation but only prior to those food additives' incorporation into food.
- Any food that is used as a means of administering the listed preparation for 'therapeutic use' (as defined by the *Therapeutic Goods Act 1989*).

All other foods would remain unaffected. Full details are in the [consultation for caffeine Poison proposal](#).

## 1.7 Reasons for preparing the Proposal

FSANZ's reasons for preparing this Proposal are detailed above.

FSANZ prepared this Proposal on 20 September 2019 after reviewing and reporting to Australian Government Ministers on the current availability and regulation of caffeine, and on options for strengthening regulations and consumer warnings in relation to pure and highly concentrated caffeine food products. FSANZ's report to Ministers recommended that FSANZ "develop and declare as urgent a proposal to amend the Code to prohibit the retail sale of pure and highly concentrated caffeine food products." This recommendation was based on FSANZ's preliminary assessment that such products pose an unacceptably high risk for consumers and that there was a need to act to protect public health and safety.

This Proposal was prepared to assess whether such products do pose an unacceptably high risk for consumers and whether, in order to protect public health and safety, the Code should be amended to prohibit the retail sale of pure and highly concentrated caffeine food products.

## 1.8 Procedure for consideration

The Proposal is being considered as an Urgent Proposal. After the Proposal was prepared on 20 September 2019, the Proposal was declared an Urgent Proposal for the purposes of Division 4 of Part 3 of the FSANZ Act.

# 2 Summary of the initial consideration

## 2.1 Risk assessment

### 2.1.1 Evaluation of caffeine health effects by FSANZ

A FSANZ Expert Working Group analysed the available literature on caffeine in 2000.

The Expert Working Group noted that a no effect level for caffeine in humans has not been established, and concluded that there was evidence of increased anxiety levels in both adults and children at doses of about 3 mg of caffeine per kilogram of bodyweight per day<sup>4</sup>. This level equates to a caffeine dose of 95 mg per day (approximately two cans of cola) in children and about 210 mg per day (approximately three cups of instant coffee) for adults.

### **2.1.2 Evaluations by other agencies**

The European Food Safety Authority (EFSA)<sup>5</sup> concluded that a total caffeine intake of 400 mg/day (5.7 mg/kg bodyweight/day) is safe for most adults. EFSA recommends that pregnant women should not consume more than 200 mg/day, or approximately 3 mg/kg bw/day, on the basis of a risk of adverse effects on foetal growth and on birthweight at higher levels of maternal consumption. EFSA concluded that there is insufficient information to determine safe levels of caffeine for children or adolescents, but that the acute intake of no concern to adults (3 mg/kg bw/day) may be used to derive acute and daily caffeine consumption values for those groups.

The United States Food and Drug Administration (US FDA),<sup>6,7</sup> also considers that 400 mg/day of caffeine is not associated with adverse effects. They warn that some medical conditions, and some medications, may increase individual sensitivity to caffeine, and advise pregnant and breastfeeding women to seek the advice of their healthcare provider. The US FDA has not set a level of caffeine for children, but noted that the American Academy of Paediatrics discourages the consumption of caffeine by children and adolescents. The US FDA estimated that severe adverse effects, such as seizures, may occur with rapid consumption of 1 200 mg caffeine or more.

The US FDA has identified products consisting of or containing only pure or highly concentrated caffeine as 'a significant public health threat', after the US FDA linked at least two recent deaths in the United States to such products. In response, the US FDA issued guidance stating that it considers certain types of these products to be adulterated and, therefore, prohibited under US food law because they present a significant or unreasonable risk of illness or injury.

### **2.1.3 Assessment of the acute health risk posed by the sale of pure and highly concentrated caffeine food products or caffeine analogues**

The effects of acute caffeine intake at doses from 20 mg to 10 000 mg are shown in Table 3.

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<http://www.foodstandards.gov.au/publications/Documents/safety%20aspects%20of%20dietary%20caffeine.pdf>

<sup>5</sup> EFSA 2015 Scientific Opinion on the safety of caffeine. EFSA Journal 13(5):4102

<sup>6</sup> [fda.gov/consumers/consumer-updates/spill-beans-how-much-caffeine-too-much](http://fda.gov/consumers/consumer-updates/spill-beans-how-much-caffeine-too-much)

<sup>7</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-highly-concentrated-caffeine-dietary-supplements>

**Table 3 Acute effects of caffeine in adults**

Acute dose (mg)	Effects/Comments
>20 mg	Self-reported positive effects on mood <sup>a</sup>
60	Measurable decrease in reaction time <sup>a</sup>
80–95	Single cup of coffee <sup>a,b</sup>
100	May delay sleep and reduce sleep duration <sup>a, c</sup>
140	Minor increase in diastolic pressure <sup>a</sup>
200	Up to this level not associated with safety concerns <sup>c</sup>
200–250	Effects including an increase in blood pressure and plasma catecholamines. Reduction in myocardial blood flow when exercising <sup>c</sup>
280	Reduction in perceived exertion during exercise <sup>c</sup>
400-500	Increase in anxiety in psychologically normal subjects <sup>c</sup>
>500	Rate of clearance of caffeine is decreased <sup>b</sup>
1200	Tachycardia, ventricular arrhythmia, seizures <sup>a,b</sup>
3 000	Lowest lethal dose identified by FSANZ <sup>a</sup>
5 000–10 000	Life-threatening dose <sup>a</sup>

<sup>a</sup>FSANZ (2000); <sup>b</sup>US FDA (2018) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-highly-concentrated-caffeine-dietary-supplements>; <sup>c</sup>EFSA (2015)

Intake of caffeine of up to 210 mg (approximately 3 mg/kg bodyweight/day) is not associated with safety concerns. Above that dose, caffeine intake is generally associated with an increase in blood pressure, plasma catecholamines and increased anxiety. At or above 1 200 mg more serious effects such as tachycardia, ventricular arrhythmia or seizures may develop and urgent medical attention may be required. Death has been reported at a dose of 3 000 mg, however it is more commonly associated with doses of around 5 000 to 10 000 mg caffeine.

Subpopulations particularly sensitive to effects of caffeine, as identified by EFSA and the US FDA, include pregnant women, lactating women, people with hypertension, people with impaired myocardial perfusion, people with certain mood disorders such as anxiety, and people who are taking *p*-synephrine.

#### *Pure caffeine powder*

FSANZ's assessment is that pure and highly concentrated caffeine food products are a high risk and pose a significant health concern. Ingestion of a 5 mL teaspoon of pure caffeine powder (approximately 3 000 mg caffeine) will result in severe health effects and could be fatal to some individuals. The risk of serious health effects is compounded by the fact that these products can require fine scales (most kitchen scales measure in grams, not milligrams) to weigh an appropriate dose.

#### *Products containing a high level of caffeine*

Products containing less than or equal to 5% caffeine are not considered to pose an unacceptably high risk to consumers. A caffeine concentration of 5% i.e. 5 000 mg/100 g is slightly higher than the levels of caffeine typically found in coffee (Table 4), and not likely to pose significant additional acute health risks to those associated with traditional coffee products.

Ingestion of a single serving of a heaped tablespoon of a caffeine powder containing 5% caffeine would be likely to deliver approximately 825 mg caffeine.<sup>8</sup> Acute doses in this range

<sup>8</sup> Assuming a poured bulk density of powdered caffeine of 0.55 g/mL (<https://www.fda.gov/inspections->

would be unlikely to cause severe health effects in healthy adults, although they could be expected to be associated with unpleasant effects such as anxiety.

The same doses may be hazardous to sensitive subpopulations such as children and pregnant women, but that risk exists with currently available natural caffeine-containing foods such as coffee.

### *Caffeine analogues*

FSANZ is aware that a number of analogues or derivatives of caffeine exist naturally or can be chemically synthesised<sup>9</sup>. The latter are used in some sports foods. FSANZ will further consider the potential health impacts of sports foods containing caffeine and caffeine analogues or derivatives, both those that occur naturally or that may be chemically synthesised, as a part of the review of Standard 2.9.4 – Formulated Supplementary Sports Foods (P1010).

## **2.2 Risk management**

FSANZ's risk assessment is that pure and highly concentrated caffeine food products pose an immediate and acute risk to consumers. FSANZ also considers that a risk management measure should be put in place quickly noting the nature of the public health risk. This action will address the immediate health risk to consumers. Broader issues with respect to the regulation of caffeine as a food by the Code or as a therapeutic good by the TGA, or as a New Zealand supplemented food, can be worked through with the jurisdictions, and also while complementary and non-regulatory long-term risk management measures (see section 2.2.5 below) are developed and then implemented.

### **2.2.1 Proposed risk management measure**

For the reasons summarised below, FSANZ considers the most appropriate response to manage the acute risk is to amend the Code to prevent these products from being sold directly to consumers. A maximum limit has the advantage of clarity in terms of what is permitted and what is not. FSANZ therefore proposes to:

- (a) set a maximum compositional limit for caffeine in food; and
- (b) set that limit at a concentration in the food of 5% (5 g/100 g) in the product presented at retail sale.

The concentration limit applies to all forms of the product supplied for retail sale such as dry products, concentrates, and liquids.

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[compliance-enforcement-and-criminal-investigations/warning-letters/smartpowders-08272015](#)) a 15 mL tablespoon (NZ) would have a mass of 8.25 g. A heaped tablespoon might be expected to have a mass of approximately 16.5 g (*c.f.* 18.5 g top scoop size for pre-workout sports supplements). If caffeine was extended with other powdered material of similar density, a heaped tablespoon of a powder containing 5% caffeine would deliver approximately 825 mg caffeine.

<sup>9</sup> Bello ML, Walker AJ, McFadden BA, Sanders DJ, Arent SM. (2019). The effects of TeaCrine® and caffeine on endurance and cognitive performance during a simulated match in high-level soccer players. *J Int Soc Sports Nutr.* 16(1):20.

Daly JW, Padgett WL, Shamim MT. (1986). Analogues of caffeine and theophylline: effect of structural alterations on affinity at adenosine receptors. *J Med Chem* 29(7):1305-8.

Murbach TS, Glavits R, Endres JR, Clewell AE, Hirka G, Vertesi A, Beres E, Pasics Szakonyine I. (2019) A toxicological assessment of methylxanthines. *The Toxicologist: Late-Breaking Supplement, Supplement to Toxicological Sciences*, 168 (1), Abstract # 3541

Müller CE, Jacobson KA. (2011) Xanthines as adenosine receptor antagonists. *Handb Exp Pharmacol.* 200:151-99.

A FSANZ review of the caffeine content of food and of data commissioned by FSANZ for a range of pre-workout sports supplements supports a 5% caffeine limit. The review's findings are summarised below in Table 4.

**Table 4 Caffeine content of pure and highly concentrated caffeine products**

Product	Caffeine g/100 g	Comments
Pure caffeine powder	94–98 g	<a href="https://www.caffeineinformer.com/caffeine-content/caffeine-powder">https://www.caffeineinformer.com/caffeine-content/caffeine-powder</a>
Instant coffee (powder or granules)	3.10–3.90 g	FSANZ analysis; 8 products by market share from top 3 brands in Australia, 2014
Espresso coffee beverage	0.26–0.66 g	FSANZ analysis; 8 cafes in Australia, 2015 (unpublished)
Coffee beverage from higher caffeine coffee beans	Up to 0.46 g/100 mL	<a href="https://www.caffeineinformer.com/strongest-coffee-brands">https://www.caffeineinformer.com/strongest-coffee-brands</a>
Guarana powder	20 g	<a href="http://bulkpowders.com.au/guarana.html">bulkpowders.com.au/guarana.html</a>
Pre-workout sport supplement powders <sup>10</sup>	0.60–4.04 g (average content in lowest and highest brands)  Highest individual analysis 5.88 g <sup>11</sup>  Label declaration (n=9) 1.07–3.25 g	Analysis of 15 popular brands available in store in Australia and on online, 2016-7.
Roasted coffee bean; ground coffee	1.2–2.2 g	Arabica and Robusta varieties
Tea, chai, instant dry powder	3.68 g	AUSNUT 2011–2013

A typical 1–2 g serve of instant coffee contains about 55–80 mg caffeine. The caffeine content of other products based on website information indicate that roasted coffee beans and ground coffee and coffee beverages contain less than 3 g/100 g caffeine. The 5% (5 g/100 g) limit is slightly higher than the level of caffeine found in coffee.

Analytical data from 15 caffeinated pre-workout sports supplement products indicated the recommended number of scoops (4.5–18.5 g/scoop) would deliver 6–19 g of product containing 91–387 mg caffeine (average/product). Some product labels additionally recommend more scoops than the baseline recommendation, so caffeine intake from these products may be higher. Some individual containers of products such as pre-workout sport supplement powders on the market might marginally exceed the proposed 5% limit.

Therefore, this limit is not expected to impact the vast majority of caffeine-containing products on the market that have a history of safe consumption and is unlikely to result in significant additional health risk. It is also consistent with the policy guidelines on the regulatory management of caffeine in the food supply.

<sup>10</sup>Desbrow B, Hall S, O'Connor H, Slater G, Barnes K, Grant G. Caffeine content of pre-workout supplements commonly used by Australian consumers. *Drug Test Anal.* 2018;1–7. <https://doi.org/10.1002/dta.2501>

<sup>11</sup>Desbrow B, Grant G, Hall S, O'Connor H, Slater G, Barnes K. Pre-workout supplements used by Australian consumers: Caffeine content and reported attitudes and behaviours. Unpublished report to FSANZ, 2017.

The proposed prohibition on foods for retail sale containing caffeine at a concentration of 5% or more will operate subject to the existing and any future express permissions for caffeine in the Code, as well as any limits or conditions imposed by and for those permissions. These include the current permissions and maximum limits for caffeine's use as a food additive in Cola type drinks and for caffeine in formulated caffeinated beverages.

FSANZ recognises that this response will in effect set a maximum limit of caffeine for general foods and that FSANZ's report to Ministers recommended that such a limit be considered after and in light of the review of Standard 2.9.4 (see section 2.2.5 below). However, after the conduct of the risk assessment, FSANZ considers that this response efficiently addresses the acute risk and is warranted.

The impact on the market of a 5% maximum caffeine concentration is expected to:

- prohibit the retail sale of high risk food products to consumers;
- enable consumers to continue to purchase and consume caffeinated food products such as espresso, coffee, caffeinated beverages including energy drinks, tea, and chocolate without concern;
- not prevent bulk caffeine purchases by beverage and pharmaceutical manufacturers permitted to use or add caffeine to their products;
- enable the continued use of caffeine as an ingredient in foods such as formulated caffeinated beverages<sup>12</sup> and sports foods; and
- not impact most types of products that may also contain caffeine, such as conventional foods or therapeutic goods.

For these reasons and those summarized below, FSANZ's preferred risk management response is to amend Standard 1.1.1 to provide that a food sold for retail sale must not contain 5% or more of caffeine. Although slightly different to the risk assessment conclusion about acute risk at greater than 5%, the draft variation sets the lower caffeine limit at 5% exactly. This allows for a more definitive cut-off and provides for more certainty given the acute toxicity risk.

Based on this assessment, FSANZ has prepared a draft variation to prohibit the retail sale of foods in which total caffeine is present in a concentration of 5% or more, in the product presented at retail sale, unless that sale or presence was expressly permitted by the Code. This limit is greater than the TGA's proposed concentration of 4% or less of total caffeine (in undivided preparations) under the [proposal to include caffeine in Schedules 4 and 6 of the Poisons Standard](#). TGA will further consider the matter now that the public consultation has closed.

FSANZ also notes the TGA has published an [intention to undertake consultation](#) on *Proposed clarification that certain sports supplements are therapeutic goods*. The proposal is likely to consider that certain sports supplements (when used, advertised or presented for supply in a particular way) are therapeutic goods. As caffeine is included in some sports supplements, FSANZ will similarly identify and assess any impacts from this consultation on the proposed FSANZ draft variation.

### 2.2.3 Other regulatory risk management measures

As explained above, FSANZ's risk assessment confirmed the acute toxicity of pure and highly concentrated caffeine food products and potential lethal outcomes associated with

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<sup>12</sup> This includes caffeinated beverages (including energy drinks) as they already have permission for the addition of caffeine at levels prescribed by the Code. These permissions also include mandatory labelling requirements to inform consumers that these products contain caffeine.

these products. In considering practical risk management options, FSANZ considered regulatory measures other than a maximum limit coupled with a prohibition on retail sale.

However, FSANZ's assessment was that other measures (for example, mandatory labelling/warning statements) are unlikely to protect public health and safety due to the following reasons:

- Pure and highly concentrated caffeine food products can be sold in packages which potentially contain thousands of servings. This means any specific directions for labelling may not address the acute toxicity associated with these products. Pure caffeine products can have the maximum 200 mg dose in 1/16th of a teaspoon, with a potentially fatal dose and the equivalent of 25–50 cups of coffee, in one teaspoon.
- These products can be shared by or dispensed to multiple users, increasing the risk of the product being separated from a labelling warning statement.
- A miniscule amount of pure or highly concentrated caffeine powder can be a lethal quantity. In addition, an average safe quantity may not be able to be accurately measured using equipment available to most consumers (e.g. standard kitchen scales). This can place an impossible onus on the consumer to measure a very small precise safe serving from a potentially lethal amount of product.
- The potential for small children in a household to access these products is a further concern. In such cases, labelling warning statements will be ineffective.

The tragic deaths in the United States and in Australia demonstrate that this is not a theoretical risk.

#### **2.2.4 Broader regulation of caffeine in the food supply**

There are a number of wider issues in relation to the regulation of caffeine in the food supply such sensitive subpopulations or the use of caffeine analogues or derivatives, particularly in sports foods.

##### *Sensitive subpopulations*

The EFSA and the US FDA have concluded that a total caffeine intake of 400 mg/day (5.7 mg/kg bodyweight/day) is safe for most adults. EFSA recommends that pregnant women should not consume more than 200 mg/day.

The 5% maximum concentration of caffeine allows a tolerance of 2-fold for adults between the USFDA/EFSA (400mg) and our proposed maximum (equivalent to 800 mg of caffeine). This dose (800 mg of caffeine) would be hazardous to sensitive subpopulations such as children and pregnant women, but the risk exists with currently available natural caffeine-containing foods (such as espresso coffee). Furthermore, caffeinated beverages (including energy drinks) have permission for the addition of caffeine at levels prescribed by the Code and this includes mandatory labelling requirements that the food contains caffeine and is not recommended for children (no defined age), pregnant or lactating women and individuals sensitive to caffeine.

##### *Caffeine analogues or derivatives*

Another issue is the potential health impacts of sports foods containing caffeine and caffeine analogues or derivatives, both those that occur naturally or that may be chemically

synthesised. FSANZ is currently reviewing the food standards relating to sports foods as part of P1010 and will consider these issues in that Proposal.

### *FSANZ approach*

On the basis of the proposed and urgent risk management measure set out above, this Proposal is not the vehicle to assess and address wider issues in relation to the clarity of the Code with respect to the regulation of caffeine in the food supply. These wider issues are best assessed and managed as part of a broader review of caffeine across the whole food supply (see section 2.2.5 below).

In the event that, after considering responses to this Call for Submissions, FSANZ decides to approve the draft variation (or an amended version of that variation), the FSANZ Act will require FSANZ to undertake a further assessment of that approved variation to decide whether it should be repealed, amended or reaffirmed. In doing so, FSANZ must undertake further public consultation. This further assessment process—which must be completed within 12 months of the draft variation’s approval—also provides an opportunity to consider some of the above-mentioned wider regulatory issues.

## **2.2.5 Additional long-term risk management measures**

FSANZ recommended a multifaceted response regarding pure and highly concentrated caffeine in its report to Ministers which was endorsed by the responsible Australian Government Minister.

In addition to developing and declaring as urgent a proposal to amend the Code to prohibit the retail sale of pure and highly concentrated caffeine food products, FSANZ’s report recommended:

- targeted research on caffeine consumption across the Australian and New Zealand population, including consumption by specific vulnerable population groups.
- The option of imposing a maximum limit of caffeine for general foods be considered in light of the outcomes of FSANZ’s review (now underway) of Standard 2.9.4 (which covers sports foods).
- Development and implementation of a coordinated inter-agency consumer information campaign on safe caffeine consumption
- Development and adoption of guidance on the regulation of high caffeine content products and pure caffeine powders to inform compliance action by regulators.

FSANZ will work in collaboration with partners in the food regulatory and other systems to progress these recommendations.

## **2.3 Risk communication**

### **2.3.1 Consultation**

Consultation is a key part of FSANZ’s standards development process. All calls for submissions are notified through a notification circular, media release, social media and through our email newsletter, Food Standards News. FSANZ will also prepare supporting materials for our existing information on food for special medical purposes web page to explain the nature of the Proposal. All interested parties are notified through FSANZ’s regular notification processes (i.e. the notification circular).



### 2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade. There are no relevant international food standards for pure and highly concentrated caffeine food products and management of these products varies internationally between countries.

FSANZ's risk assessment confirmed that there is an immediate and acute risk posed by the sale of pure or highly purified forms of caffeine to consumers. Ingestion of small amounts of these substances can result in severe health effects, including death.

FSANZ considered the most appropriate response to that risk was to prepare a draft variation to prohibit the retail sale of foods in which total caffeine is present in a concentration of 5% or more, in the product presented at retail sale, unless that sale or presence was expressly permitted by the Code.

In FSANZ's view amending the Code to prohibit pure and highly concentrated caffeine food products is unlikely to have a significant effect on international trade because of the following:

- These are highly specialised products that comprise a very small segment of the market.
- The proposed measure does not prevent wholesale bulk caffeine purchases by beverage and pharmaceutical manufacturers permitted to use or add caffeine to their products.
- There are no impacts for most types of products that contain caffeine, such as conventional foods or therapeutic goods. Consumers can continue to purchase and consume caffeinated food products such as espresso, coffee, caffeinated beverages including energy drinks, tea, and chocolate without concern.

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

## 2.4 Issues

FSANZ also had regard to the following matters when considering this Proposal and in preparing the draft variation.

### 2.4.1 Whether the measure's costs may outweigh its benefits

FSANZ had regard to the costs and benefits to the community, government or industry that may arise from developing the proposed measure in a manner that was commensurate with the time and data that was available.

After doing so, FSANZ decided on a regulatory approach (prohibition on retail sale for foods containing 5% caffeine or more) on the basis that it was satisfied that there was an identified immediate risk to public health and safety that could result in further harm and deaths. Non-regulatory options were not considered appropriate given the serious potential consequences of the consumption of pure and highly concentrated caffeine powder and ease with which over-dosing could occur in consumers.

Initial examinations of the market indicated that pure and highly concentrated caffeine powder is a niche product (for direct consumer use) that would be unlikely to make up a large percentage of any specific businesses sales and that its purchase for use in the manufacture of food and beverages will not be prohibited. On this basis it is likely that the benefits will outweigh the costs.<sup>13</sup>

On 4 October 2019, the OBPR advised the Authority that a COAG Regulation Impact Statement was not required to inform the decision by FSANZ to approve, amend or reject the draft variation. However, if the draft variation is approved following public consultation, a regulatory impact statement (RIS) may be required as part of the reassessment of that variation.

#### **2.4.2 Whether there are other more cost effective measures available**

For the reasons listed in this Report, FSANZ is satisfied that a prohibition, as set out in the proposed draft variation, is the most cost-effective food regulatory measure (whether available to FSANZ or not) to address the identified risk.

#### **2.4.3 Whether there are any relevant New Zealand standards**

The proposed draft variation will apply in both Australia and New Zealand.

New Zealand food law includes the *New Zealand Supplemented Food Standard 2016*. How that Standard operates is discussed in section 1.4.1 above.

The Standard provides that specific provisions of the Code do not apply or are modified in their application to supplemented food in New Zealand. The Standard currently states that paragraphs 1.1.1—10(5)(b), (6)(b) and (f) of the Code do not apply to supplemented food. As such, all other provisions of section 1.1.1—10 of the Code do apply.

The draft variation prepared by FSANZ, if approved, will insert a new provision into section 1.1.1—10 to prohibit the retail sale of food containing 5% or more caffeine.

FSANZ understands that the above means that the new provision and the related prohibition, if approved, will apply to supplemented food unless the New Zealand Government decides to amend the Standard to dis-apply the new provision and remove the prohibition.

#### **2.4.4 FSANZ's statutory objectives in standards development**

FSANZ also had regard to the three objectives in subsection 18(1) of the FSANZ Act during its initial consideration.

##### **2.4.4.1 Protection of public health and safety**

The FSANZ Act requires FSANZ to have regard to the fact that the primary objective in standards development is the protection of public health and safety. FSANZ concluded that the proposed prohibition as provided by the draft variation would best meet this statutory objective.

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<sup>13</sup> Based on international and Australian research a credible estimate of the **value of statistical life** is \$4.5m in 2018 dollars. Whilst attaching a value to a life is challenging to many it does highlight in this instance that the consumer and producer surplus from the sale of these products is unlikely to exceed the potential loss.

#### **2.4.4.2 The provision of adequate information relating to food to enable consumers to make informed choices**

The issue of additional labelling for pure and highly concentrated caffeine food products to enable consumers to make informed decisions was considered. For the reasons outlined in this report, FSANZ was not satisfied that labelling was an appropriate risk management measure.

#### **2.4.4.3 The prevention of misleading or deceptive conduct**

The proposed prohibition protects consumers unaware of risks of consumption of pure and highly concentrated caffeine food products, thereby supporting the objective of prevention of misleading or deceptive conduct.

#### **2.4.5 Subsection 18(2) considerations**

FSANZ has also had regard to:

- ***the need for standards to be based on risk analysis using the best available scientific evidence***

FSANZ has assessed and characterised the risk from the consumption of pure and highly concentrated caffeine food products. This risk assessment has considered currently available information (national and international), including animal and human toxicity, relevant to the safety of pure and highly concentrated caffeine food products.

- ***the promotion of consistency between domestic and international food standards***

There are no consistent international standards for caffeine. Nor is there a consistent international regulatory approach (see section 1.5 above). The US FDA has issued guidance stating its position that the sale of certain pure and highly concentrated caffeine food products are prohibited under US food law because of the significant public health and safety risks they pose.

FSANZ also considers that the proposed response outlined in this Report is justified on the grounds of protection of public health and safety.

- ***the desirability of an efficient and internationally competitive food industry***

Australia and New Zealand's reputation as a producer of safe food is an important factor in being regarded as an internationally reputable food industry.

There are no relevant international standards and amending the Code to prohibit the sale of pure and highly concentrated caffeine food products is unlikely to have a significant effect on international trade because these highly specialised products comprise a very small segment of the market.

- ***the promotion of fair trading in food***

No fair trading issues have been identified for the purposes of this Proposal.

- ***any written policy guidelines formulated by the Forum on Food Regulation.***

The Forum (then convening as the Australia and New Zealand Food Regulation Ministerial Council) agreed to a new policy guideline on the regulatory management of caffeine in the food supply in June 2014<sup>14</sup>. FSANZ has had regard to the current policy guidelines on caffeine issued by the Forum.

### **3 Draft variation**

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal. A draft explanatory statement is at Attachment B.

#### **Attachments**

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

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<sup>14</sup> The policy guidance is available at <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Caffeine-to-Foods>

## Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



### Food Standards (Proposal P1054 – Pure and highly concentrated caffeine products) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Insert name and position of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

**1 Name**

This instrument is the *Food Standards (Proposal P1054 – Pure and highly caffeinated products) Variation*.

**2 Variation to a standard in the *Australia New Zealand Food Standards Code***

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

**3 Commencement**

The variation commences on the date of gazettal.

**Schedule**

**[1] Standard 1.1.1** is varied by omitting paragraph 1.1.1—10(5)(f), substituting

- (f) if the food is for retail sale – raw apricot kernels;
- (g) if the food is for retail sale – a food in which caffeine is present at a concentration of 5% or more.

## Attachment B – Draft Explanatory Statement

### 1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1054 to amend the Code to prohibit the retail sale of pure and highly concentrated caffeine food products.

Following its preparation, Proposal P1054 was declared an Urgent Proposal for the purposes of the Division 4 of Part 3 of the FSANZ Act.

The Authority considered the Proposal in accordance with section 96 of the FSANZ Act and has prepared a draft variation.

### 2. Purpose

The Authority has prepared a draft variation to amend Standard 1.1.1 of the Code to prohibit the retail sale of food that contains 5% (5 g/100 g) or more of caffeine.

### 3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

### 4. Consultation

In accordance with the procedure in Division 4 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1054 will include one round of public consultation following an initial consideration and the preparation of a draft variation and associated assessment summary.

After that public consultation, the Authority will consider whether to approve, amend or reject the draft variation, having regard to all submissions received. If the Authority approves the draft variation or an amended draft variation, the FSANZ Act requires the Authority then to assess that variation in accordance with Subdivision B of Division 4 of Part 3 of the FSANZ Act. Further public consultation is required as a part of that assessment.

The Authority submitted a preliminary assessment to the Office of Best Practice Regulator (OBPR) seeking advice on a regulatory intervention in relation to Proposal P1054. On 4 October 2019, the OBPR advised the Authority that a COAG Regulation Impact Statement was not required to inform the decision by the Authority to approve, amend or reject the draft variation.

## 5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

## 6. Variation

Item [1.1] amends Standard 1.1.1 by inserting a new paragraph into subsection 1.1.1—10 (5).

The new paragraph is paragraph 1.1.1—10 (5)(g). The new paragraph provides that, unless expressly permitted by the Code, a food for retail sale cannot be a food that contains caffeine in a concentration of 5% or more of the food for sale.

The new paragraph will apply this maximum limit for caffeine to all foods for retail sale.

The reference to 'caffeine' in paragraph 1.1.1—10 (5)(g) includes caffeine that occurs or is present in the food for sale naturally. The exception provided by subsection 1.1.1—10(7) of the Code for foods (such as caffeine) that occur or are present in the food for sale naturally does not apply to a prohibition imposed by subsection 1.1.1—10(5) and, therefore, to the prohibition imposed by the new paragraph.

The new paragraph cannot - and does not - itself constitute a permission for the purposes of the Code to add caffeine to all foods (e.g., for the purposes of the prohibitions imposed by other paragraphs in subsection 1.1.1—10 (5))

As mentioned above, the prohibition imposed by the new paragraph will operate subject to the Code's other provisions, including existing and future express permissions for caffeine in the Code and any limits or conditions imposed by and for those permissions. For example -

- Standards 1.1.1 and 1.3.1 and Schedule 15 provide an express permission for caffeine to be used as a food additive in Cola type drinks subject to a maximum permitted level of 145 mg/kg. The new paragraph will not override this express permission or maximum permitted limit or otherwise constitute a permission for a 5% maximum limit for caffeine in Cola type drinks.
- Standards 1.1.1 and 1.3.1 and Schedule 15 also provide an express permission for 'permitted flavouring substances, excluding quinine and caffeine' to be used as a food additive in certain foods. The new paragraph will not override caffeine's express exclusion from this specific food additive permission or otherwise permit caffeine's use as a food additive in those foods.
- Standard 2.6.4 provides that a formulated caffeinated beverage must contain no less than 145 mg/L and no more than 320 mg/L of caffeine in total, from any source. The new paragraph will not override this specific maximum limit for caffeine in formulated caffeinated beverages or otherwise constitute a permission for a 5% maximum limit for caffeine in formulated caffeinated beverages.



## Appendix A: Regulation of caffeine internationally

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### Pure and highly concentrated caffeine products

#### *United States of America (USA)*

In a statement dated April 2018<sup>15</sup>, the US Food and Drug Administration (FDA) noted that many products consisting of only or primarily pure or highly concentrated caffeine are sold as dietary supplements. They consider some such products to be adulterated under the *Federal Food, Drug, and Cosmetic Act 1988* (FD&C Act), because they are dietary supplements that present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labelling or, if no conditions for use are suggested or recommended, under ordinary conditions of use.

The FDA issued 'guidance' stating it considers the following products to be 'adulterated' for the purposes of the FD&C Act: Powdered Dietary Supplements and Liquid Dietary Supplements containing pure or highly concentrated powdered caffeine and that are sold in bulk such that the consumer is required to separate out a safe serving from a potentially lethal amount.

The FD&C Act provides that a food is 'adulterated' for its purposes if, among other things, it contains a dietary ingredient that presents a **significant or unreasonable risk of illness or injury** under:

- (a) the conditions of use recommended in labeling
- (b) ordinary conditions of use if no conditions of use are suggested or recommended in labelling.

The FD&C Act prohibits interstate commerce of adulterated products.

US regulators also have enforcement tools in relation to adulterated food, e.g, seizure and destruction, injunctions preventing manufacturing or distribution or requesting a recall. Enforcement action is usually preceded by a Warning Letter from FDA to the manufacturer or distributor of the adulterated product. The Guidance states that Warning Letters had been issued for various products.

The FDA guidance states that the following are not considered to be adulterated:

- A. Dietary supplements sold in solid dosage forms, such as tablets or capsules that do not provide an excessive amount of caffeine per item. Products in these forms eliminate the need for a consumer to accurately measure the appropriate serving.
- B. Dietary supplements containing powdered or liquid caffeine (either diluted or undiluted) that are sold in premeasured packets or containers, with each premeasured unit containing an amount of caffeine that is not excessive. Products that are sold in pre-

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<sup>15</sup> Available at <https://www.federalregister.gov/documents/2018/04/16/2018-07836/highly-concentrated-caffeine-in-dietary-supplements-guidance-for-industry-availability> and <https://www.fda.gov/food/dietary-supplement-products-ingredients/pure-and-highly-concentrated-caffeine> Accessed 6 August 2019

measured quantities eliminate the need for a consumer to measure the appropriate amount.

- C. Bulk powdered or liquid caffeine dietary supplement products that have been significantly diluted to low enough concentrations of caffeine, such that a reasonably foreseeable measurement error, misreading of the directions, or misunderstanding about the nature of the product.

#### *Canada*

Pure and highly concentrated caffeine products are permitted for retail sale. Caffeine shots (based on a specified size limit of a package containing 90 mL or less (or up to 125 mL depending on representation)), caffeine pills and caffeine powder typically used as a sports supplement are regulated as licensed natural health products under the Natural Health Products Regulations<sup>16</sup>. Registered caffeine-containing natural health products are listed on an on-line database<sup>17</sup> by Health Canada.

The regulations have a general requirement for certain information to be included on a label of a natural health product, including each medicinal ingredient (such as caffeine), the recommended use or purpose, recommended dose, recommended duration of use (if any) and any risk information.

#### *European Union*

Caffeine is added as an ingredient to food supplements<sup>18</sup>, in which it is often used in combination with synephrine mainly for weight loss and enhanced sports performance.

It is the responsibility of the competent authorities of the Member States to classify a product taking into account its characteristics (e.g whether a pure caffeine powder is a food supplement or medicine).

Food supplements are regulated under [Directive 2002/46/EC](#). Member States may develop regulation to implement this Directive. This Directive does not include compositional rules for caffeine. There is no permission to add caffeine as a flavouring to food supplements. In the absence of EU harmonised rules, national rules setting out which substances may be used and their conditions of use, may exist.

The amount of the substances with a nutritional or physiological effect (such as caffeine) present in food supplements shall be declared on the label as well as the portion of the product recommended for daily consumption and a warning not to exceed the stated recommended daily dose (the Directive requires the setting of maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer). A statement to the effect that the products should be stored out of the reach of young children is also required.

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<sup>16</sup> Available at <https://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/> Accessed 6 August 2019

<sup>17</sup> <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/applications-submissions/product-licensing/licensed-natural-health-products-database.html> Accessed 6 August 2019

<sup>18</sup> **food supplements** means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities

The Commission, on its own initiative or at the request of a Member State, can prohibit, restrict or put under Union scrutiny the use of other substances added to foods (including food supplements). Caffeine has not been prohibited, restricted or put under scrutiny to date<sup>19</sup>.

## Other foods containing caffeine

### *United states of America (USA)*

In the USA, additives such as caffeine 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 recognized as safe' (GRAS) (i.e. substances generally recognised to be safe by qualified experts)<sup>20</sup>. The FDA Code of Federal Regulations<sup>21</sup>, states that caffeine is GRAS when used in cola-type beverages and that the level of caffeine in these types of beverages must not exceed 0.02 per cent (i.e. 200 ppm).

Caffeine may also be used as an ingredient in other foods provided it has been determined as GRAS for its intended use in those foods. To date, no GRAS determinations for caffeine have been located via an internet search and there are none listed on the USA inventory of GRAS notices, except for one pending for *Ilex guayusa* leaf extract<sup>22</sup>.

Any food that contains added caffeine must have caffeine listed as an ingredient, but the actual quantity of caffeine does not have to be stated on the label. There are no other labelling requirements specifically for caffeine in the USA<sup>23</sup>.

### *Canada*

The addition of caffeine to food is regulated as a food additive. Carbonated soft drinks can contain caffeine, i.e. cola type beverages up to 200 ppm and non-alcoholic carbonated water-based flavoured and sweetened beverages other than cola type beverages up to 150 ppm<sup>24</sup>. Requests to add caffeine to foods such as snacks have not been accepted to date (personal communication).

As a food additive, caffeine would need to be declared in the list of ingredients<sup>25</sup>. No quantitative labelling is required however manufacturers are encouraged to label the amount of caffeine per stated serving size<sup>26</sup>. This does not apply to foods/ingredients that are well

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<sup>19</sup> [https://ec.europa.eu/food/safety/labelling\\_nutrition/vitamins\\_minerals\\_en](https://ec.europa.eu/food/safety/labelling_nutrition/vitamins_minerals_en)

<sup>20</sup> <https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras> Accessed 6 August 2019

<sup>21</sup> 21CFR182.1180 available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=182.1180> Accessed 6 August 2019

<sup>22</sup> GRAS notices inventory is available at <https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices>

<sup>23</sup> Leah S Rosenfeld, Jeremy J Mihalov, Susan J Carlson, Antonia Mattia, 2014. Regulatory Status of caffeine in the United States. Nutrition Reviews, Volume 72, Issue suppl 1, 1 October 2014, pp 23-33

<sup>24</sup> List of Permitted Food Additives with Other Accepted Uses (Lists of Permitted Food Additives) available at <https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/8-other-accepted-uses.html> incorporated by reference in the [Marketing Authorization for Food Additives with Other Accepted Uses](#), enabled by the Food and Drugs Act. Accessed 22 July 2019

<sup>25</sup> Food and Drug Regulations B.01.008 available at [https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,\\_c.\\_870/page-5.html#docCont](https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-5.html#docCont) Accessed 22 July 2019

<sup>26</sup> Preliminary Guidance for Industry on the Labelling of Caffeine Content in Prepackaged Foods

known sources of caffeine (e.g. coffee, tea and chocolate). There is no regulatory requirement to identify the presence of or amount of caffeine for natural sources of caffeine. Health Canada intends to consult in the next few months on making quantitative caffeine labelling a required condition of use of any food additive caffeine (this would be applicable to carbonated soft drinks) (personal communication).

Caffeinated products that are pre-packaged, ready-to-consume, in a container containing 90 mL or less (or up to 125 mL depending on representation, as the typical container size for food beverages is 125 mL), and meant to be consumed in a single dose, shall be classified as natural health products.

Caffeinated energy drinks are also regulated as a food (before 2011 they were regulated as a natural health product). The regulatory requirements for these drinks have not yet been finalised as there are some outstanding information gaps. All caffeinated energy drinks are therefore still being regulated under the Temporary Marketing Authorization (TMA) framework<sup>27</sup>. There are certain eligibility criteria associated with the TMA. The caffeine content of caffeinated energy drinks can be between 200-400 ppm. Alcoholic versions cannot be sold. Caffeinated energy drinks must be labelled with:

- a statement that they have a high caffeine content
- a quantitative declaration of total caffeine from all sources
- the statements:
  - Not recommended for children, pregnant or breastfeeding women and individuals sensitive to caffeine.
  - Do not mix with alcohol.
- a statement regarding the maximum number of containers/servings per day. This limit on the number of containers/servings must not result in the daily maximum limit being exceeded for any added vitamins, minerals or amino acids.

### *European Union*

The use of caffeine as a flavouring substance in food is subject to restrictions of use in certain food categories (dairy products and analogues 70 mg/kg, edible ices 70 mg/kg, confectionery 100 mg/g, non alcoholic beverages 150 mg/kg)<sup>28</sup>.

The addition of substances to food that have a nutritional or physiological effect is regulated by [Regulation \(EC\) No 1925/2006](#). This regulation does not include compositional rules for caffeine. In the absence of EU harmonised rules, national rules setting out which substances may be used and their conditions of use, may exist.

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(March 2010) available at <https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/preliminary-guidance-industry-labelling-caffeine-content-prepackaged-foods-march-2010.html> accessed 22 July 2019

<sup>27</sup> TMA letters are regulatory instruments that allow for non-compliant foods that meet all the requirements of a TMA to be sold before the regulatory amendments are made. The purpose of the TMA is to gather specific data that will support an amendment to the *Food and Drug Regulations*. <https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/category-specific-guidance-temporary-marketing-authorization-caffeinated-energy-drinks.html#s5.3.3>

<sup>28</sup> [https://webgate.ec.europa.eu/foods\\_system/main/index.cfm?event=substance.view&identifier=2452](https://webgate.ec.europa.eu/foods_system/main/index.cfm?event=substance.view&identifier=2452)

## OFFICIAL

All pre-packaged foods must bear a list of ingredients where the ingredients are designated by their specific name ([Regulation \(EU\) No 1169/2011](#)). Caffeine used as a flavouring in food shall be mentioned by name 'caffeine' in the list of ingredients immediately after the term 'flavouring(s)'.

Beverages with caffeine over 150 mL/L must be labelled with the statements *High caffeine content. Not recommended for children or pregnant or breast-feeding women*. The actual caffeine content must also be on the label.

Foods other than beverages where caffeine is added with a physiological purpose must be labelled *Contains caffeine. Not recommended for children or pregnant women*. The actual caffeine content must also be on the label.

In 2018 the UK government consulted on ending the sale of energy drinks to children<sup>29</sup>. According to media reports (July 2019), the government has confirmed it will ban the sale of energy drinks to children under 16.

The European Food Safety Authority (EFSA) has prepared a [scientific opinion on the safety of caffeine](#). In its opinion published in 2015 EFSA concluded that single doses of caffeine up to 200 mg as well as caffeine intakes from all sources up to 400 mg per day consumed throughout the day do not give rise to safety concerns for healthy adults in the general population, except pregnant women.

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<sup>29</sup> <https://consultations.dh.gov.uk/obesity/sale-of-energy-drinks-to-children/>