12 December 2019
[105 - 19]

Final consideration report – Urgent Proposal P1054

Pure and highly concentrated caffeine products

Food Standards Australia New Zealand (FSANZ) has approved a draft food regulatory measure after considering an urgent proposal to prohibit the retail sale of pure and highly concentrated caffeine food products.

On 30 October 2019, FSANZ prepared and sought submissions on a draft variation and published an associated initial consideration report. FSANZ received 24 submissions.

FSANZ approved the variation on 12 December 2019.

The variation took effect on public notice.

This Report is provided pursuant to section 97 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Table of contents

Executive summary

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

FSANZ prepared this Proposal as an emergency interim response following its review and report to Australian Government Ministers in August 2019, which found these products pose an immediate and acute risk to consumers. The ingestion of small amounts of these substances can result in severe health effects, including death.

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 due to the unacceptably high risk for consumers and 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 highly 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. The risk assessment formed the basis of a call for submission and proposed a draft variation to prohibit the retail sale of foods in which total caffeine is present in a concentration of 5% or more.

Currently, the Code prevents caffeine's addition to or use in food only in specific circumstances or for specific purposes, i.e. as a food additive, processing aid or nutritive substance. 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 use of pure and highly concentrated caffeine food products generally.

For the reasons outlined in this report, FSANZ considered the most appropriate response to mitigate that risk was to amend and approve the prepared draft variation to prohibit the retail sale of foods in which total caffeine is present in a concentration of 1% (1 000 mg/100 mL, liquid form) or 5% (5 000 mg/100g, powder and gel form) 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[1].

FSANZ must, within 12 months of notification of the approved variation, undertake a full assessment of the variation. This review includes a call for public comment to either reaffirm its approval of the variation or prepare a proposal to amend, replace or revoke that variation. In approving the variation the Board noted work is underway to ensure longer term alignment between the TGA and FSANZ regimes in relation to caffeine.

[1] 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 urgent Proposal was prepared to prohibit the retail sale of pure and highly concentrated caffeine food products which pose an immediate and acute risk to consumer health and safety.

1.2 The current standards

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

Table 1: Code provisions for caffeine permission in food

Product	Current risk management/amount in food
Any food containing caffeine as an ingredient	> A Code requirement to declare added caffeine in the ingredient list.
Formulated caffeinated beverages (energy drinks)	> 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).
Formulated supplementary sports foods (e.g. pre-workout supplements, protein powders)	> 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 *Therapeutic Goods Act 1989.* > 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.
Cola type drinks	> The Code restricts the amount of caffeine (total caffeine must not exceed 145 mg/kg). > Labelling advisory statement 'contains caffeine'.
Food containing guarana or extracts of guarana	> Labelling advisory statement 'contains caffeine'

In summary:

- The Code does not expressly prohibit the addition or use of caffeine in food; nor does the Code expressly prohibit the sale of pure or highly concentrated caffeine.

- 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) and in formulated caffeinated beverages. In both cases, this use is subject to compositional and labelling requirements.

- 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 their presence 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 a food additive, a processing aid or a nutritive substance.

- 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' cannot be used in food other than in cola type drinks
    - caffeine cannot be used in food as 'a processing aid' or as 'a nutritive substance'.

1.3 Imported food 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 risk food and are scheduled in the *Imported Food Control Order 2019* or are surveillance food.

Orders to classify food are made by the Minister based on risk advice from FSANZ. Food may be classified as 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 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 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 (TTMRA) 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 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 in the nutrition information panel. 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.

Section 3.4.3 explains how the *New Zealand Supplemented Food Standard 2016* will interact with the approved variation.

1.5 International approaches – caffeine in or as a food

There is no consistent approach to the regulation of caffeine for sale to consumers in the United States of America (USA), Canada and the European Union 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
USA	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.
Canada	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.
European Union	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’.

1.6 Other issues: food-medicine interface

The regulation of caffeine in Australia 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 would best mitigate the potential risks. This approach was considered the most pragmatic way 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 Ministerial request to review pure and highly concentrated caffeine products, 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 4% (immediately) and 1% (by 2 March 2021). Divided preparations (such as tablets and capsules) must not contain a concentration of caffeine greater than 33%. Both types of preparation have associated mg/day limits. 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 published a proposal to include caffeine in Schedule 4 and 6 of the Poisons Standard.

Schedule 6[2] 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. 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 was discussed at the previous Joint Advisory Committee on Medicines and Chemicals Scheduling. Under the nominated timeframes for that 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.

FSANZ also understands that the Poisons Standards provides exemptions for substances that are packed and sold solely for industrial or manufacturing purposes.

Full details are in the consultation for caffeine Poison proposal.

1.7 Reasons for preparing the Proposal

FSANZ prepared this Proposal following its review of pure and highly concentrated caffeine products which found these products pose an immediate and acute risk to Australian consumers and, as such, there was a need to act to protect public health and safety.

The 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 following the death of a young man in New South Wales attributed to acute caffeine toxicity associated with the consumption of a caffeine powder.

[2] https://www.tga.gov.au/publication/national-guideline-retail-storage-schedule-6-and-schedule-7-poisons

As caffeine can be regulated as a both a food and a therapeutic good, 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 would best mitigate the risk.

In theCall for Submissions, FSANZ sought feedback on its initial consideration of the Proposal, specifically the proposed maximum limit for all foods up to a 5% concentration and whether this limit was likely to have any unintended consequences on products currently in the market that do not present an immediate and acute risk.

1.8 Procedure for consideration

The Proposal was 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.

1.9 Decision

The draft variation as proposed following initial consideration was approved with three amendments in order to :

- Include an additional variation to Schedule 1.1.1 that the retail sale of pure and highly concentrated caffeine food products in liquid form must not contain 1% caffeine or more.
- Clarify that Section 1.1.1—9 does not apply to the approved variation and there is no 12 month stock in trade exemption.

The approved variation, as varied after consideration of submissions, is at Attachment A. The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation. The draft variation on which submissions were sought is at Attachment C.

The variation will take effect on public notice. Subsection 97(5) of the FSANZ Act provides that the commencement date of the variation is the date that public notice of the variation's approval was given in accordance with subsection 97(4) of that Act.

The FSANZ Act provides that FSANZ must, within 12 months of public notice of the approval of the variation, undertake a full assessment of that variation, call for public comment and either reaffirm its approval of the variation or prepare a proposal to amend, replace or revoke that variation.

In approving the variation the Board noted work is underway to ensure longer term alignment between the TGA and FSANZ regimes in relation to caffeine.

2 Summary of the submissions

Twenty four submissions were received. All submissions supported the regulation of caffeine food products. However, some submitters did not agree with the proposed approach to doing this.

Key themes identified through the consultation process related to:

- Risk to public health and safety:
  - The 5% limit is set too high and may not protect public health and safety – particularly if the limit results in an increase in the amount and variety of food products containing caffeine.
  - A high caffeine-containing liquid product needs a lower concentration limit in the Code.
  - Small volume portion controlled products containing more than 5% caffeine but delivering safe doses of caffeine should be exempted.

- Interpretation of current permission/prohibition for caffeine in the Code:
  - The draft variation appears to provide – or may be perceived as – a broad permission to add caffeine to all foods up to a limit of 5%.
  - It is jurisdictions' view that the intention of the Code was to prohibit the addition of caffeine to food unless expressly permitted.
  - The revision of the Code in 2014 as part of Proposal P1025 inadvertently led to caffeine being permitted in food when not used a food additive (e.g. as a stimulant).
  - The draft variation is inconsistent with the Ministerial Policy Guidelines for the Regulatory Management of Caffeine in the Food Supply.

- The proposed limit of up to 5% should align with the TGA concentration limit (currently proposed at 4%) for ease of compliance and enforcement.

- The draft variation is not needed as the States and Territory food Acts will prohibit the sale of a food that is not safe and suitable.

- The draft variation may impact on the use of 'unsuitable food' provisions by State and Territory food Acts.

- The need to notify World Trade Organisation members of the draft variation to identify trade impacts.

- Other general issues raised:
  - format or the presentation of caffeine-containing foods
  - the lack of an advisory statement requirement
  - stock in trade provisions under Standard 1.1.1—9
  - the draft variation capture of imported foods for personal use.

See **Attachment D** for the summary of issues and FSANZ's responses to each of the above issues.

2.1 Summary of FSANZ's position on issues identified in submissions

FSANZ considered all submissions and acknowledges the limited time to respond to the Call for Submissions Report due to the urgent nature of this Proposal.

FSANZ has engaged jurisdictions and industry during the course of this urgent proposal noting the purpose of this urgent proposal is to address the acute and immediate risk of pure caffeine powders and highly concentrated food products that present an unacceptable risk to consumers.

In addition, and importantly, as part of the call for comment, FSANZ has also sought to identify any products on the market that present no safety risk that may be inadvertently captured with the proposed limit of up to 5%.

FSANZ notes that overall industry were supportive of the draft variation

Some sports supplement industry submissions requested a higher limit (6.5 - 7%) to accommodate specific products. However, these submissions did not provide evidence to support that the products should be considered safe and due to the acute toxicity risk, FSANZ's position is that the level set in accordance with the risk assessment should remain.

Submissions from jurisdiction, while generally supportive of regulation of caffeine in the Code, proposed alternative approaches.

In conclusion, this proposal was raised as an interim and urgent measure to address the immediate and acute toxicity risk from caffeine powders and high caffeine content food products. In response to the submissions received, FSANZ included high caffeine-containing liquid products in the approved variation (see updated risk assessment and management section below).

Attachment D sets out FSANZ's response to each of the specific issues raised by submitters.

The urgent proposal process allows for a review of the decision within 12 months. This will allow FSANZ time to consider any broader issues raised by jurisdictions and industry that do not relate to the acute and immediate risk of pure and highly concentrated products.

3 Summary of the final consideration

3.1 Risk assessment

As explained in the Call For Submissions, FSANZ conducted a risk assessment to inform its decision. The objective was to establish a concentration of caffeine in a powder or a liquid concentrate that is unlikely to be associated with serious adverse health effects following accidental or adventitious ingestion of caffeine in highly caffeinated products. Such products may require consumers to 'self-measure' caffeine servings.

The assessment did not extend to a consideration of potential health effects of caffeine following long-term or low dose exposure to caffeine. These health effects have been considered previously by FSANZ, and other international agencies, as summarised below.

3.1.1 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[3]. This

3

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.

3.1.2 Evaluations by other agencies

The European Food Safety Authority (EFSA)[4] 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[5],[6] (US FDA) 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.

3.1.3 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.

Table 3: Acute effects of caffeine in adults

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

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

[4] EFSA 2015 Scientific Opinion on the safety of caffeine. EFSA Journal 13(5):4102

[5] fda.gov/consumers/consumer-updates/spill-beans-how-much-caffeine-too-much

[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-highly-concentrrated-caffeine-dietary-supplements

Acute dose (mg)	Effects/Comments
1200	Tachycardia, ventricular arrhythmia, seizures[a,b]
3 000	Lowest lethal dose identified by FSANZ[a]
5 000–10 000	Life-threatening dose[a]

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

Intake of caffeine of up to 210 mg (approximately 3 mg/kg bw) 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 high risk and a significant health concern. Ingestion of a teaspoon of pure caffeine powder (approximately 3 200 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.

Bulk powder products containing a high level of caffeine

Bulk powders 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.[7] Acute doses in this range 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.

Other products identified through the submission process

In addition to bulk powdered caffeine, a number of other caffeine products have been identified through the public submission process. These may be available in retail shops or

[7] Assuming a poured bulk density of powdered caffeine of 0.55 g/mL (https://www.fda.gov/inspections-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.

through the internet, including concentrated solutions, and individually packaged products such as strips and chewable items.

Liquid caffeine concentrate products

Concentrated caffeine solutions, which may be used to make energy drinks by some consumers, are of high risk and pose a significant health concern. Accidental ingestion of liquid products may occur more easily than bulk powder products.

FSANZ considers that for concentrated caffeine solutions, a maximum permitted level of 1% w/v caffeine is required to protect public health and safety. This is based on the intended delivery of 100 mg of caffeine in a volume of 10 mL of a liquid product.

A quantity of 82.5 mL of a 1% solution would be required to ingest 825 mg of caffeine, the same amount of caffeine as contained in a heaped tablespoon of a bulk powdered product with a concentration of 5% caffeine.

Individually packaged caffeine products

Individually and divided packaged caffeine products are expected to have a different risk profile to bulk powders and liquid concentrates because the total caffeine exposure is likely to be limited by the form of the packaging. These could include strips, chewables and gels.

FSANZ notes that no safety concerns are associated with doses of up to 200 mg caffeine.

Caffeine analogues

FSANZ is aware that a number of analogues or derivatives of caffeine exist naturally or can be chemically synthesised[8].

[8] 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 methylliberine. 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.

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 P1010.

3.2 Risk management

FSANZ's risk assessment is that pure and highly concentrated caffeine food products posed an immediate and acute risk to consumers. FSANZ also considered that a risk management measure should be put in place quickly noting the nature of the public health risk. This action addressed 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 3.2.5 below) are developed and then implemented.

3.2.1 Risk management measures

For the reasons summarised below, FSANZ's considered the most appropriate response to manage the acute risk was to amend the Code to prevent pure and highly concentrated caffeine 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.

Powders, gels, gums and other non-liquid products

A FSANZ review of the caffeine content of products and of data commissioned by FSANZ for a range of pre-workout sports supplements supports a 5% caffeine limit for powders, gels, gums and other non-liquid products. The review's findings are summarised below in Table 4.

Table 4: Caffeine content of pure, highly concentrated and other caffeine products at the food medicine interface

Product	Caffeine g/100 g or 100 mL	Sample websites /Comments
Pure caffeine powder	94–98 g	https://www.caffeineinformer.com/caffeine-content/caffeine-powder
Guarana powder	20 g	bulkpowders.com.au/guarana.html
Caffeine strips[9]	19 g (individually wrapped single portions, 40 mg caffeine per strip)	https://www.revviesenergy.com/?gclid=EAIaIQobChMIgLih-pD45QIVjA4rCh12tQnjEAAYASAAEgIhf_D_BwE
Pre-workout sport supplement powders[10]	4.04–0.60 g (average content in highest to lowest brands) Highest individual analysis 5.88 g[11] Label declaration (n=9) 1.07–3.25 g	Analysis of 15 popular brands available in store in Australia and on online, 2016–17.
Caffeine chewing gum	4.0–4.3 g	https://militaryenergygum.com/products/arctic-mint-tray

[9] Revvies energy strips™ are flavoured caffeine impregnated strips that are individually wrapped and sold in packs of 5 (211 mg each, 40 mg caffeine) with a label statement *exceeding 5 serves per day may cause harm*.

[10] 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

[11] 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.

Product	Caffeine g/100 g or 100 mL	Sample websites /Comments
Tea, chai, instant dry powder	3.68 g	AUSNUT 2011–2013
Instant coffee (powder or granules)	3.10–3.90 g	FSANZ analysis; 8 products by market share from top 3 brands in Australia, 2014
Liquid caffeine concentrate	0.8–1.7 g	https://liquidcaffeine.com/
Roasted coffee bean; ground coffee	1.2–2.2 g	Arabica and Robusta varieties
Coffee beverage from higher caffeine coffee beans	Up to 0.46 g	https://www.caffeineinformer.com/strongest-coffee-brands
Energy shots (liquid)	Up to 0.7 g	https://www.caffeineinformer.com/the-caffeine-database
Espresso coffee beverage	0.26–0.66 g	FSANZ analysis; 8 cafes in Australia, 2015 (unpublished)
Cola/energy beverage concentrate (liquid)	0.3–0.6 g	https://www.sodastream.com.au/flavours-1/energy/xstream-440
Gels	0.27	https://www.zipvit.co.uk/zv7c-caffeine-energy-gel-uk.html
Chewable confectionery	0.2	https://bonkbreaker.com/collections/energy-chews/products/strawberry-energy-chews-with-caffeine

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 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

The prohibition on liquid and powder and gel forms foods for retail sale 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.

Concentrated liquid solutions of caffeine

Submitters brought to FSANZ's attention concerns over the safety of liquid products containing high levels of caffeine.

FSANZ undertook a further review of products on the Internet and found bulk liquid caffeine concentrates up to 1.7% caffeine. On the basis of an updated risk assessment, FSANZ concluded that a safe level of 1% is appropriate for these types of products.

Other forms of caffeine above 5%

From Table 4, only two types of product: guarana powder and caffeine strips exceed 5% caffeine that would be prohibited from sale as a food.

Products such as light weight caffeinated strips are portion controlled as single individually packaged serves; they are sold in small quantities per pack with labelling instructions and advisory statements for use. Therefore they pose a lower risk than bulk products where the consumer determines the serve size since no acute safety concerns have been identified at doses of up to 200 mg caffeine.

These products are currently imported into New Zealand from the United Kingdom and regulated as a New Zealand supplemented food and consequently sold in both Australia and New Zealand. The regulatory status of these products (as foods or therapeutic goods) has not been determined by Australian authorities and FSANZ is not aware of any domestic manufacturer of these products.

The approved variation to the Code will not affect trans-Tasman trade in these products therefore no exemption, at this stage, was included in the variation.

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 3.2.4 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 1% maximum concentration in liquid products and 5% in powders and other non-liquid preparations 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 sale in Australia or New Zealand of caffeinated strips
- 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[12] and sports foods
- 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 was to amend Standard 1.1.1 to provide that a food sold for retail sale must not contain total caffeine present in a concentration of 1% (liquid form) or more or 5% (powder or other non-liquid form) or more. Although slightly different to the risk assessment conclusion about acute risk at greater than 1 or 5%, the approved variation sets the lower caffeine limit at 1 or 5% exactly. This allows for a more definitive cut-off and provides for more certainty given the acute toxicity risk.

Based on this assessment, and for the reasons set out in this report, FSANZ has approved a variation to the Code to prohibit the retail sale of foods in which total caffeine is present in a concentration 1% (liquid form) or 5% (powder or other dry form), in the product presented at retail sale, unless that sale or presence was expressly permitted by the Code.

The limit for non-liquid food 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

[12] 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.

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 approved variation in future work on caffeine.

3.2.2 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 fatal outcomes associated with 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 small 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.

3.2.3 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 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. However, the EFSA/FDA assessments are based on normal consumption of caffeine in products on a daily basis.

Whereas, FSANZ's assessment considered what levels of pure caffeine products should be prohibited on the basis of unacceptable health risks associated with accidental or inadvertent ingestion.

Therefore, while FSANZ acknowledges that the concentration limits for adults would be hazardous to sensitive subpopulations such as children and pregnant women, that 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

For the reasons set out in this Report, this urgent Proposal is not the vehicle to assess and address these wider issues in relation 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 3.2.4 below).

The FSANZ Act requires FSANZ to undertake a further assessment of the approved variation to decide whether that variation – and the amendments it made – 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 variation's approval—also provides an opportunity to consider some of the above-mentioned wider regulatory issues.

3.2.4 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) or an alternative proposal.

- 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.

3.3 Risk communication

3.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. In relation to this urgent proposal, the call for submissions was notified through notification circulars, a media release, social media and updated web content. FSANZ also consulted with the Working Group which was established to assist in the initial review. Members include food regulatory authorities from the Australian Commonwealth, the Australian States and Territories, New Zealand's Ministry for Primary Industries, and New Zealand's Medicines and Medical Devices Safety Authority.

Industry and key stakeholders were also notified of the release of the call for submissions through email.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal in the short timeframe. Every submission on this proposal was considered by the FSANZ Board. All comments were valued and contribute to the rigour of our assessment.

3.4 FSANZ Act considerations

In addition to the submissions received, FSANZ had regard to the following matters when considering approving the draft variation.

3.4.1 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 the measure.

After doing so, FSANZ decided on a regulatory approach (prohibition on retail sale) 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 its use and ease with which a mistake could be made by a consumer.

Initial examinations of the market indicated that it 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.[13]

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.

[13] 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.

3.4.2 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 approved variation, was the most cost-effective food regulatory measure to address the identified risk.

3.4.3 Whether there are any relevant New Zealand standards

The approved variation will apply in both Australia and New Zealand.

FSANZ understands that the amendments made by the approved variation to Standard 1.1.1 of the Code will not have immediate effect in New Zealand. That is, the amendments must first be considered and then adopted by the New Zealand Government in accordance with the *Food Act 2014* (NZ).

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 *New Zealand Supplemented Food Standard 2016* 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 approved variation inserts a new provision into section 1.1.1—10 to prohibit the retail sale of food containing 1% or 5% or more caffeine.

The above means that, if and when the New Zealand Government decides under the *Food Act 2014* (Cth) to adopt the approved variation, the new provision in section 1.1.1—10 and its prohibition will apply to supplemented food unless the New Zealand Government decides to amend the *New Zealand Supplemented Food Standard 2016* to dis-apply that provision.

3.4.4 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.

3.4.4.1 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 prohibition as provided by the approved variation best met this statutory objective.

3.4.4.2 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.

3.4.4.3 The prevention of misleading or deceptive conduct

The prohibition imposed by the approved variation protects new 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.

3.4.5 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***

The approved variation was based on and reflects a risk assessment that relied on the best available scientific evidence. FSANZ's risk assessment 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 its response 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[14]. FSANZ had regard to the current Policy Guideline on caffeine issued by the Forum before making its decision to approve the draft variation.

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

.

4 Approved variation

The approved variation to the Code is at Attachment A and will take effect on notification. An explanatory statement is at Attachment B and the draft variation to the Australia New Zealand Food Standards Code (Call for Submissions) at Attachment C.

5 Review of the approved variation

The approved variation was considered and approved as part of an Urgent Proposal under sections 95 to 97 of the FSANZ Act. As such, the FSANZ Act provides that FSANZ must now undertake a full assessment of the approved variation, call for public comment and then either reaffirm its approval of the variation or prepare a proposal to amend, replace or revoke that variation. This process must be completed within 12 months of notification of the approved variation.

Attachments

A. Approved variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement
C. Draft variation to the *Australia New Zealand Food Standards Code* (Call for Submissions)
D. Summary of issues raised in submissions

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

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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

---

The Board of Food Standards Australia New Zealand gives public notice of the approval of this variation under section 97 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 Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

Public notice of the approval of the variation will be given in the *Food Standards Australia New Zealand Notification Circular* Number XXX published and issued on XXXX. This means that this date is the date of public notice 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 public notice of the approval of the variation.

4 Transitional arrangements

Section 1.1.1–9 of the *Australia New Zealand Food Standards Code* does not apply to the variations made by this instrument.

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:

(i) 5% or greater—if the food is a solid or semi-solid food; and

(ii) 1% or greater—if the food is a liquid food.

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 sections 96 and 97 of the FSANZ Act and has approved a variation.

2. Purpose

The Authority has approved a variation to amend Standard 1.1.1 of the Code to prohibit total caffeine present in a concentration of 1% (1 000 mg/100 mL, liquid form) or 5% (5 000 mg/100g, powder and gel or other dry form) or more in the product presented at retail sale.

3. Documents incorporated by reference

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

4. Consultation

The Authority considered the Proposal in accordance with the procedure in Division 4 of Part 3 of the FSANZ Act. That consideration included 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 had regard to all submissions received and approved an amended version of the draft variation.

The approved variation must be reviewed by the Authority within 12 months of its notification 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.

A Regulation Impact Statement was not required. 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

(i) 5% or more of the food for sale if that food is a solid or semi-solid food; or
(ii) 1% or more of the food for sale if that food is a liquid.

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

An example of a semi-solid food is a gel.

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)) or by subsection 1.1.1—10 (6)).

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

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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

---

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 D – Summary of issues raised in submissions

Issue	Raised by:	FSANZ Response
The proposed variation appears to provide - or may be perceived as - a broad permission to add caffeine to all foods up to a limit of 5%. Such a permission could mean • any substance can be added to any food provided it is added other than as a nutritive substance, food additive or processing aid • any food can contain up to 5% caffeine • any food additive currently restricted to certain foods, can be added to any food, and in any quantity, provided it is added for function other than as a nutritive substance, food additive or processing aid. This could increase the availability of caffeine in the food supply and high caffeine products which could pose health and safety risks.	Vic, SA, Qld, WA	Noted. FSANZ does not agree that the variation can or will constitute a permission to add caffeine to all foods up to 5%. The variation itself is stated expressly to be a prohibition, not a permission. FSANZ remains satisfied that it will operate as such. Nor is there any relevant prohibition in the Code that the approved variation could provide an exception or permission for. The Code relies on the Food Acts to have any legal effect. Section 21 of the Food Acts requires food for sale to comply with a requirement of the Code. That is, there must first be a relevant requirement stated in the Code for there to be a prohibition or indeed anything to have legal or regulatory effect under section 21. There is no requirement stated in the Code that expressly imposes a general prohibition on the addition of caffeine to food or the presence of caffeine in any or all food. Silence, or the absence of a stated requirement in the Code, does not and cannot of itself constitute a prohibition. The above was captured in the public CFS, in the public review report to Ministers and in briefing papers provided to jurisdictions for the purposes of developing that report To date, no jurisdiction has been able to identify any such text or a provision in the Code. (See also FSANZ's response to South Australia below.) The Food Act offences prohibiting the sale of unsafe food continue to apply.

Issue	Raised by:	FSANZ Response
Such a permission may complicate jurisdictions' use of offences provisions in the Food Acts. In terms of the 'unsuitable' offence provisions, such a permission (or the absence of a prohibition) could lead to an argument that synthetically produced caffeine would no longer be – for the purposes of those offence provisions - *'a biological or chemical agent, or other matter or substance, that is foreign to the nature of the food'.* Jurisdictions may be required to default to the higher bar of *'unsafe food'* before potentially hazardous product could be removed from the market, even if was associated with human health impacts among sensitive sections of the population (e.g. young children, teenagers, pregnant women).	NSW Food Authority	Noted. See FSANZ's response above. FSANZ notes that, to the extent that the Code does not prohibit the addition of caffeine to food per se now, any such argument could be run now. See FSANZ response below about using this urgent emergency response to address wider regulatory issues.
FSANZ's interpretation of the Code is perverse and incorrect. The Code currently prohibits the addition of caffeine to foods unless expressly permitted. Evidence for the existence of this prohibition can be inferred from: • Enforcement decisions rejecting foods due to their caffeine content • FRSC 2013 policy documents that describe historic and current permissions for caffeine being limited to cola drinks, formulated caffeinated beverages and naturally occurring caffeine. • The *Ministerial Policy Guideline for the Regulatory Management of Caffeine in the Food Supply*, which	Victorian Departments of Health and Human Services and of Jobs, Precincts and Regions	Noted. FSANZ does not agree. See FSANZ's response above. In order for such a prohibition to exist, there must first be text in the Code that expressly prohibits the addition of caffeine to any food. As explained above, no such text exists. Nor has any jurisdiction been able to identify any such text or a provision in the Code. (See also FSANZ's response to South Australia below.) FSANZ's understanding is that the enforcement decisions and policy documents in question predate the commencement of the current Code. FSANZ had regard to the *Ministerial Policy Guideline for the Regulatory Management of Caffeine in the Food Supply* in making its decision.

Issue	Raised by:	FSANZ Response
discusses how the regulation of caffeine needs to consider intakes from all sources and the most vulnerable and caffeine sensitive populations. • The existence of Standard 2.6.4 - Formulated Caffeinated Beverages. That Standard would not be necessary if the Code permitted caffeine to added to any food for reasons other than as a food additive.		Standard 2.6.4 imposes specific compositional and labelling requirements on specific products, namely those products that meet the definition of a Formulated Caffeinated Beverage.
FSANZ's interpretation of the Code and approach in this Proposal has created a serious regulatory gap that needs to be urgently fixed.	Qld Health Vic Health	Noted. FSANZ does not agree. The Code does not contain currently any provision that expressly prohibits the addition of caffeine to all food. See FSANZ's responses above. To the extent any regulatory gap may exist, it exists because of that fact, not because of any interpretation given to the Code by FSANZ.
Instead of approving the draft variation, FSANZ should act to now ban any addition of caffeine to food unless expressly permitted by the Code. Various alternate drafting to impose such a prohibition was suggested by jurisdictions.	QLD Health NSW Food Authority VIC Health WA Health	Noted. The Code does not currently impose a general prohibition on caffeine in any or all food. Introduction of such a ban, which would criminalise the sale of particular food products, is a major step. FSANZ's response to this issue must be in accordance with the FSANZ Act and Australian administrative law. The latter requires, among other things, that FSANZ's response – and any variation to the Code - based on the best available scientific evidence and a risk assessment. FSANZ's decision and the approved variation is a specific and interim response to an immediate public health and safety risk. FSANZ is satisfied for the reasons set out in this report that the approved variation is appropriate *interim* response to address that risk. Broader issues around added caffeine in the food supply – and the issue of a general prohibition of caffeine in food - is best addressed at a later stage in

Issue	Raised by:	FSANZ Response
		measured manner and after public consultation with all stakeholders – as recommended in FSANZ's review report to Ministers. The FSANZ Act requires FSANZ to review its decision and decide within 12 months whether to confirm, reject or amend the approved variation. FSANZ considers this review is a more appropriate vehicle for consideration of whether and how to impose a general prohibition on caffeine in food in Australia and New Zealand. In responding to this issue and the tragic death of a young man in NSW, FSANZ established a Working Group including food regulatory authorities from the 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.
The revision of the Code in 2014 as part of P1025 inadvertently led to caffeine being permitted in food when not used a food additive (e.g. as a stimulant).	• WA Health • VIC Dept. of Health and Human Services	Noted. Prior to the revision of the Code in 2015, clause 2 of the then Standard 1.3.1 imposed a general prohibition on the addition of a 'food additive'. The term 'food additive' was not defined in the then Code itself. However, the Purpose section of the old version of Standard 1.3.1 stated was intended to constitute a 'food additive' for the purposes of that Standard at that time. That is - > 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 5. It or its by-products may remain in the food (emphasis added). This statement or definition is similar to the Code's current definition of what constitutes a food additive or use as a food additive. That is, addition to food for a prescribed and specific technological function.

Issue	Raised by:	FSANZ Response
		No jurisdiction raised this concern when they were consulted on and agreed to the current Code.
The proposed variation is not required as the Food Acts of the States and territories will prohibit the sale of a food that is not safe and suitable	SA	Noted. FSANZ notes no other jurisdiction raised this issue during the consultation process.
The proposed variation is not required as caffeine has not been approved as a novel food in the Food standards Code. Alternatively, caffeine as a food could be given permission as a novel food with limits on its use.	SA	Noted. FSANZ does not share South Australia's view. Reliance on the novel food provisions of the Code alone to regulate caffeine's presence in or addition to food was considered and rejected in the FSANZ review report. As stated in the review report, the status of caffeine as a novel food remains arguable and untested by food regulators and the courts. The novel food provisions of the Code are the subject of a review in Proposal P1024. The publically available Consultation Paper and Call for Submissions issued for that Proposal detail various difficulties in relying on those provisions. FSANZ notes no other jurisdiction raised this issue during the consultation process.
The proposed variation is not required as • the use of caffeine is expressly prohibited by the Code other than where expressly permitted; and • there is currently no express permission in the Code to use caffeine other than in Cola drinks to	SA	Noted. FSANZ does not share South Australia's view. See FSANZ's responses above.

Issue	Raised by:	FSANZ Response
provide the function of flavouring and in formulated caffeinated beverages as an ingredient.		
The proposed variation is not required as • Caffeine is a food additive listed in Schedule 15. • Caffeine does not have an ADI and so is considered safe and is limited by GMP. • Addition of a food additive to food is expressly prohibited other than where expressly permitted in the schedules and is required to be used consistent with good manufacturing practice (GMP). • Food additives are placed in a "positive list" of permitted substances to be added to food which regulates there safe use. So if a substance is not performing a technological function in the food, it is not permitted to be used unless expressly permitted. • This means that the Code effectively bans the use of the food additive unless there is a permission found elsewhere in the Code. • The alternative would mean any food additive when not used to perform a technological function could be added at any level in a food. A manufacturer could decide that it was adding a food additive for any other purpose that a food additive as described as functioning, without	SA.	Noted. FSANZ does not share South Australia's view for the reasons stated on pages 10 of its review report to Ministers. That is - Paragraph 1.1.1—10(6)(a) of the Code prohibits the use of substances as food additives unless expressly permitted. This prohibition applies only to a substances that falls with the Code's definition of what constitutes a food additive. This definition is provided by sections 1.1.2—2(3) and 1.1.2—12. These state that a substance is a food additive or 'used as a food additive' in relation to food if <u>both</u> the following criteria are met. – The substance is added to food to perform one or more of the technological functions listed in Schedule 14 of the Code; <u>and</u> – The substance is a substance identified in section 1.1.2—11 (2). If the first criterion is not met, the substance cannot be a food additive for the purposes of the Code's prohibition on the use of a food additives. This means that if caffeine is added to a food to perform a function other than one listed in Schedule 14 then logically and legally it cannot be a substance 'used as a food additive' for the purposes of the Code. That is, that use is not subject to or restricted by the prohibition imposed by section 1.1.1—10(6)(a). As stated above, FSANZ is not aware of any other provision of the Code that prohibits the addition to food of a 'food additive' other than for a technological function listed in Schedule 14 of the Code. Nor has any other jurisdiction identified such a provision. As stated above, it is not FSANZ's interpretation or this Proposal which has

Issue	Raised by:	FSANZ Response
limitation. The food additive standard would fail to operate as it was intended to work • This proposal would therefore create a regulatory gap. • Alternatively, the food additives standard could be amended by adding a condition to the food additive permissions to restrict the retail sale of caffeine.		created any regulatory gap. It is the absence of relevant provisions or requirements in the Code itself. See FSANZ's responses above.
The proposed variation is not required as Standard 1.1.1 regulates the use of caffeine for other purposes other than a food additive, etc, and requires an express permission.	SA	Noted. FSANZ does not share South Australia's view. The general prohibitions imposed by Standard 1.1.1 on the use of substances as food additives, processing aids and nutritive substances, unless expressly permitted, prevent the addition or use of caffeine in food only in specific circumstances or for specific purposes. As explained above, the Code does not contain a requirement that expressly prohibits the addition or use of caffeine in food per se. Nor does the Code contain a requirement that expressly prohibits the sale of pure or highly concentrated caffeine as a food.
Any change to the Code regarding caffeine must comply with the Caffeine Policy guidelines	SA	FSANZ does not share South Australia's view. FSANZ's response must be in accordance with the FSANZ Act and Australian administrative law. The FSANZ Act requires FSANZ - in its assessment - to have regard to the *Ministerial Policy Guideline for the Regulatory Management of Caffeine in the Food Supply*. However, the Guideline remains only one factor, among many others, that FSANZ is required to consider and weigh when deciding whether and how to amend the Code. See section 59 and paragraph 18(2)(e) of the FSANZ Act.

Issue	Raised by:	FSANZ Response
		The Ministerial Policy Guideline itself is not binding on FSANZ. It does not and cannot prevent FSANZ exercising the independent statutory discretion conferred on FSANZ by the FSANZ Act. Nor can the Guideline constrain FSANZ to reach a particular decision; nor can it prevent FSANZ taking all relevant considerations into account. FSANZ has regard to the Ministerial Policy Guideline for the Regulatory Management of Caffeine in the Food Supply in it assessment and in its decision to approve the draft variation. See section 3.4.5 of this report.
A percentage limit of caffeine in food is difficult to enforce. An MPL means the maximum permitted level, measured (unless otherwise indicated) in mg/kg is more appropriate and consistent with the Code.	SA	Noted. The approved variation is also consistent with the approach being considered by the TGA.
Section 1.1.1—9 should not apply to the proposed variation to provide a 12 month stock in trade exemption.	NSW, NZMPI	Noted. The approved variation states that section 1.1.1–9 does not apply.
The proposed draft variation is inconsistent with TGA proposed limit.	Vic. NSW, Qld	Noted. The TGA's proposed concentration limit of 4% is still undergoing scheduling assessment and consultation. The TGA have been provided with FSANZ's scientific evidence and risk assessment for consideration and potential alignment.
The proposed draft variation does not **address the issue of access to concentrated caffeine products.** Its broad concentration limit creates problems with the dose of caffeine readily available depending on the form of the food.	Vic	Noted. FSANZ has considered foods currently on the market, notably instant coffees that contain the highest levels of caffeine of permitted foods, and have set the levels so that those products remain legal.
The 5% threshold is too high and does not appear to include a sufficient margin of safety - particularly for sensitive population groups such as children.	NSW, Qld, WA	Noted. In the risk management section, FSANZ acknowledges that the limit would

Issue	Raised by:	FSANZ Response
		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). FSANZ notes the approved variation is an interim urgent measure to address the immediate and acute toxicity risk from caffeine powders and high caffeine content food products. FSANZ will consider this issue as part of the review of its decision which will be undertaken within 12 months
The proposed variation is inconsistent with the *Ministerial Policy Guidelines for the Regulatory Management of Caffeine in the Food Supply* The Guidelines requires regard be given to vulnerable population groups and to the exposure to caffeine from all dietary sources. Allowing caffeine to be present at up to 5% in food for retail sale, may pose a risk to health, particularly for vulnerable population groups, including children, adolescents, pregnant and lactating woman and caffeine sensitive consumers.	WA Qld	Noted. In making its decision, FSANZ had regard to the *Ministerial Policy Guidelines for the Regulatory Management of Caffeine in the Food Supply,* to the risk to vulnerable population groups and to the exposure to caffeine from all dietary sources. See the risk assessment and risk management sections of the Call for Submissions and of this Approval Report.
The proposed variation does not take into account the type of food (liquid, powder, gel) and the manner in which the food is consumed.	Qld, WA, NZMPI	Noted. The approved variation imposes a 1% concentration limit for liquid foods and a 5% concentration for solid and semi-solid foods.
The proposed variation is inconsistent with the current restrictions in place for caffeine in formulated caffeinated *beverages and kola beverages*	WA	FSANZ does not agree. See responses above.
Food represented as a caffeinated beverage is limited to 0.032% caffeine and requires advisory statement, whereas other foods and beverages can contain any amount (up to 5%) under the current proposal with no advisory statement.	WA	Noted. As stated in section 3.2.2 of the Approval report, FSANZ's assessment was that measures such as mandatory labelling/warning statements are unlikely to protect public health and safety for the specific products in question.

Issue	Raised by:	FSANZ Response
A WTO notification should be made in case there are significant impacts on trade identified.	NZMPI NZFGC	Noted. WTO notifications will be made. Legal advice to FSANZ is that the variation can be approved without prior WTO notification. That is, as - • The relevant WTO agreements – the Technical Barriers to Trade (TBT) Agreement and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) – allow urgent measures required to protect public health to be adopted without prior notification. See Article 2.10 of the TBT Agreement and clause 6 of Annex B to the SPS Agreement. • The variation is an urgent interim measure required to protect public health for the purposes of Article 2.10 and clause 6. FSANZ's risk assessment has confirmed the existence of an immediate and acute risk to consumers posed by the sale of pure or highly purified forms of caffeine. Ingestion of small amounts of these substances can result in severe health effects, including death. FSANZ will therefore make WTO notifications under both Article 2.10 and clause 6. The view of WTO members can and will be sought, considered and addressed in FSANZ's review of approved variation – which must be completed within 12 months. As explained above, FSANZ must review the approved variation and decide whether to re-affirm, amend or repeal the approved variation. This decision must be made within 12 months of the date that the approved variation was approved. Public consultation must occur before that decision is made. FSANZ will also seek and take WTO members views into account before making that decision.
Further consideration should be given to the format or the presentation of caffeine-containing foods, for example	NZMPI High Performance	Noted.

Issue	Raised by:	FSANZ Response
individually packaged in pre-measured single servings as they pose less risk than products requiring a consumer to self-measure servings. NZMPI identified a product under the New Zealand supplemented food that is sold in Australia and New Zealand. This product provides 40 mg dose caffeine in a 211 mg strip which equates to about 19% caffeine concentration, which if regarded as a food, would be prohibited under the draft proposal. High performance sport NZ also raised similar concerns relating to caffeine strips, tablets, chewing gums, sports gels and caffeine shots.	Sport-NZ	See sections 1.4 and 3.4.3 of this Approval Report , which considers issues relating to the *Food Act 2014* (NZ), the *New Zealand Supplemented Food Standard 2016* and the TTMRA.
Supports the Proposal and suggested that the average consumer would be more able to understand the proposed measure in the Code, if it was simplified to average cups of coffee, tea etc. as per standard drinks for alcohol.	Individual consumer (Mary Duff)	Noted. FSANZ will update the current fact sheet on the website to assist consumers understand the significance of the concentration limits.
Supports the proposal and encourages collaboration between FSANZ and the TGA on the regulation of pure or highly concentrated caffeine products in Australia.	Dietitians Association of Australia	Noted.
Supports the proposal. Due to the acute toxicity concerns, this situation should have been addressed earlier and supports more monitoring should be undertaken on packaged food.	Individual consumer (Helen Marrero)	Noted. FSANZ regularly monitors the food supply under the ATDS and will consider if there is a need to increase monitoring of pure or highly concentrated caffeine products in the food supply.
Supports the proposal and notes that the department has requested advice from FSANZ on sports supplements containing pure and highly concentrated caffeine. If FSANZ agrees that the risk is in a category of medium or high, then this will facilitate amendments to the Imported Food Control order to enable the department to enforce the prohibition	Department of Agriculture	Noted.

Issue	Raised by:	FSANZ Response
proposed in the draft variation.		
Due to insufficient time to consider this proposal, reserves the right to amend their position. Highlighted the following: • Differences between the TGA proposed concentration limit of 4% (decreasing to 1% after March 2012) and FSANZ's proposed limit. • The draft variation does not capture imported foods, in particular, those for personal use or prevent imports from NZ via the TTMRA. • Excessive overregulation may lead to more imports via personal use and we encourage FSANZ to consider a balance between consumer demand and PH&S. • Prefer that FSANZ adopts the TGA limits for undivided preparations in powders or liquids. • lack of clarity at the food-medicine interface, encourage the TGA and FSANZ to collaborate more effectively on these shared issues.	Complementary Medicines Australia	Noted. See FSANZ responses above relating to the difference between the TGA and FSANZ's concentration limits. See sections 1.3 and 1.4 of the Approval Report relating to imported food. FSANZ and the TGA are continuing to liaise on the issue of caffeine regulation.
Agrees that there is a public health and safety risk but recommends that consideration be given to a higher limit due to the following: • Syrups and sodas sold at retail for dilution by the consumer, may be removed from the market as they may be >5%.	New Zealand Food and Grocery Council (NZFGC)	Noted. FSANZ remains satisfied for the reasons set out in this report that the limit set is appropriate to protect health and not affect the majority of caffeine-containing products on the market. .
Supports the measure to reduce the risk associated with consumption of highly concentrated products, but suggested that the level is set too high due to safety concerns and prefers a lower limit, as there is no ergogenic reason for levels to be >2%.	Sports Dietitians Australia	Noted. FSANZ remains satisfied for the reasons set out in this report that the limit set is appropriate.

Issue	Raised by:	FSANZ Response
Referred to the use of caffeine in dietary supplements, its wide use in sport and provided FSANZ with several key papers detailing these use of concentrated caffeine products commonly used in sport. Concerned that removing specific products could drive purchases 'underground' and products that are not tested, which would increase risk for consumers. Provided FSANZ with a list of products with links currently used under supervision within the NZ high performance system. Highlighted that the removal of products within months of the Tokyo Olympics poses a disruption to well-developed strategies that have been practiced by NZ athletes.	High performance sport New Zealand (HPSNZ)	Noted. See sections 1.4 and 3.4.3 of this Approval Report , which considers issues relating to the *Food Act 2014* (NZ), the *New Zealand Supplemented Food Standard 2016* and the TTMRA.
Supports the Proposal and the future recommendations from FSANZ identified in the recent report to Minister's. The proposed 5% limit will not impact on current and future caffeine-containing foods and beverages.	Australian Beverage Council Limited (ABCL)	Noted.
Supports the Proposal along with the continued monitoring of caffeine in the food supply, including vulnerable population groups.	New Zealand Beverages Council	Noted.
Support the Proposal but recommend that the draft variation is amended to reflect that it only applies to caffeinated powders/liquids which require reconstitution or dilution by the consumer. Recommend a second draft variation to cover all other ready to consume caffeinated foods and beverages.	University of Notre Dame Australia and Telethon Kids Institute	Noted. The 1 and 5% maximum permitted level was based on FSANZ's risk assessment summarised in the CFS, including its assessment of the best available evidence. FSANZ variation imposes a 5% compositional limit in relation to all caffeine –

Issue	Raised by:	FSANZ Response
Propose the prohibition of all Formulated Caffeinated Beverages under standard 2.6.4 of the Code on the basis of the significant negative impact on children's health.		naturally occurring and added. This is consistent with the findings of the risk assessment and reflects the requirements of the FSANZ Act. Broader issues around added caffeine in the food supply can be best addressed in a measured manner at a later stage – as recommended in FSANZ's review report to Ministers.
Supports the Proposal.	Body science	Noted.
Supports the principle that products should be safe for consumers, proposes 7% limit based on fat burner potential at this dose.	Global Link nutrition Nutrition Warehouse Supplement Warehouse Vitamin King	Noted. FSANZ remains satisfied for the reasons set out in this report that the limit set is appropriate. See responses above.
Supports the principle that products should be safe for consumers, proposes 6.5% limit.	Switch Nutrition	Noted. See responses above.

Appendix A: Regulation of caffeine internationally

Pure and highly concentrated caffeine products

United States of America (USA)

In a statement dated April 2018[15], 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, injections 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-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

[15] 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

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[16]. Registered caffeine-containing natural health products are listed on an on-line database[17] 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[18], 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.

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

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

[17] 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

[18] **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

food supplements). Caffeine has not been prohibited, restricted or put under scrutiny to date[19].

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)[20]. The FDA Code of Federal Regulations[21], 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 *Illex guayusa* leaf extract[22].

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[23].

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[24]. 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[25]. No quantitative labelling is required however manufacturers are encouraged to label the amount of caffeine per stated serving size[26]. This does not apply to foods/ingredients that are well

---

[19] https://ec.europa.eu/food/safety/labelling_nutrition/vitamins_minerals_en

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

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

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

[23] 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 supple 1, 1 October 2014, pp 23-33

[24] 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

[25] 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 Accessed 22 July 2019

[26] Preliminary Guidance for Industry on the Labelling of Caffeine Content in Prepackaged Foods (March 2010) available at https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/preliminary-guidance-industry-labelling-caffeine-content-

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[27]. 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)[28].

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.

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)'.

---

prepackaged-foods-march-2010.html accessed 22 July 2019

[27] 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

[28] https://webgate.ec.europa.eu/foods_system/main/index.cfm?event=substance.view&identifier=2452

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[29]. 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.

[29] https://consultations.dh.gov.uk/obesity/sale-of-energy-drinks-to-children/