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

4 March 2025
331-25

2nd Call for submissions – Proposal P1056
Caffeine review

Food Standards Australia New Zealand (FSANZ) has assessed a proposal to review permissions for caffeine in sports foods and in the general food supply and considered the risk caffeine poses to sensitive sub-populations and has prepared a draft food regulatory measure. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this proposal need to be made through the Consultation Hub (https://consultations.foodstandards.gov.au/).

Submissions on this proposal will be published on the Consultation Hub. Submissions will be published following consultation and before the next stage in the statutory assessment process.

We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at Making a submission.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 15 April 2025

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

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

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

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Table of contents

Supporting documents

The following documents, which informed the assessment of this proposal, are available on the FSANZ Consultations Hub and the P1056 page on the FSANZ website:

SD1 Safety assessment of caffeine
SD2 Dietary Intake Assessment
SD3 Social science Literature Review
SD4 Assessment of caffeine and sports performance
SD5 Cost and Benefits Analysis

Executive summary

Proposal P1056 – Caffeine review was raised by Food Standards Australia New Zealand (FSANZ) following the completion of Urgent Proposal P1054 – Pure and highly concentrated caffeine products. P1054 amended the Australia New Zealand Food Standards Code (the Code) to prohibit the retail sale of a food in which caffeine is present at a concentration of:

- 1% or more of the food if that food is a liquid,
- 5% or more of the food if that food is a solid or semi-solid food.

Proposal P1056 considers whether additional measures are required in relation to the regulation of caffeine in the Australian and New Zealand food supply in order to protect public health and safety. Specifically, the proposal examines:

- the addition of caffeine to Formulated Supplementary Sports Foods (FSSF) and other foods in the general food supply, and
- the extent of the risk posed to vulnerable sub-populations and whether and how any such risk should be managed.

The proposal is being assessed under FSANZ's major procedure, which requires two rounds of statutory public consultation. The first round of consultation occurred in December 2022 and sought submissions on FSANZ's assessment of P1056 and preliminary conclusions.

FSANZ's risk assessment identified that single intakes of 210 mg caffeine and up to 400 mg/ day (5.7 mg/kg bw/day) were not associated with adverse effects in non-pregnant adults. Caffeine intake in pregnant women should be limited to 200 mg of caffeine per day. In children, consumption of up to 3 mg/kg bw/day[1] is safe although there is some evidence of increased anxiety at this dose.

A dietary exposure assessment showed that up to 6% of Australian adults (aged 20 years and above) and 2% of New Zealand adults (aged 15 years and above), as well as up to 15% of pregnant women, were exceeding the safe limit of caffeine intake. FSANZ's social science assessment found there was evidence some specific sub-populations typically consumed more than the safe limit of caffeine (e.g., university students, nurse and midwife shift workers).

P1054 identified there is a risk of acute poisoning from inadvertent consumption of concentrated caffeine products. These types of products pose higher risks to infants and children due to the low body weight of infants and children relative to adults.

To ensure the protection of public health and safety, and after considering all submissions received to the 1st CFS, FSANZ prepared a draft variation to the Code that, if approved, would:

- prohibit the retail sale of caffeine as a food unless expressly permitted by the Code
- prohibit a food for retail sale from containing caffeine as an ingredient or component unless expressly permitted by the Code
- in light of the above, remove the current Code prohibition on a food for retail sale containing caffeine in a concentration of:
  - 5% or more of the food for sale if that food is a solid or semi-solid food; or
  - 1% or more of the food for sale if that food is a liquid
- expressly permit FSSF to contain caffeine up to 200 mg in a one-day quantity (the amount of FSSF which is to be consumed in one day in accordance with directions specified on the label) and

[1] Expressed per kg bodyweight due to the rapid growth of children. Assuming body weights of 13 kg for a 1-3 year old and 22kg for a 4-8 year old (NHMRC, 2006), the respective approximate safe intakes for children would be 39 mg/day and 66 mg/day.

- set new compositional, packaging and labelling requirements for FSSF, including a requirement that a FSSF must not contain caffeine at a concentration of
    - 5% or more for a FSSF in a powdered form; or
    - 1% or more for a FSSF in a liquid form.

The separate general prohibition on pure and highly concentrated caffeinated products for retail sale (the 1 and 5% concentration limits set by P1054) would not be required as FSANZ's proposed approach would prohibit such products. FSANZ has proposed a specific approach for managing caffeine concentrations in FSSF including one-day quantity permissions, concentration limits, and packaging requirements for small volume FSSF, liquids and powders.

The proposed amendments in P1056 would not impact the sale of foods such as coffee, teas and chocolate that naturally contain caffeine. The compositional requirements for these foods are included in the Code in Standard 2.10.4 – Miscellaneous standards for other foods. Subsection 1.1.1—10(7) of the Code allows for the presence of caffeine by natural occurrence in a compliant food or ingredient. This means the proposed amendments would have no impact on food businesses' ability to add an ingredient that contains caffeine by natural occurrence to other foods, for example adding coffee or chocolate to a cake or confectionery.

The proposed amendments will establish clear requirements for the addition of caffeine to foods, and the use of caffeine as a food in Australia and New Zealand to ensure the continued protection of public health and safety, particularly for vulnerable sub-populations.

FSANZ now seeks submissions on the draft variation to the Code. Submissions received in response will inform FSANZ's decision on whether to approve, amend or reject the proposed draft variation. If approved by FSANZ, the draft variation will be referred to the Food Ministers' Meeting for consideration and endorsement.

Abbreviations and Glossary

Term	Description
bw	Body weight
CFS	Call for submissions
Code	Australia New Zealand Food Standards Code
EC	European Commission
EGCG	Epigallocatechin gallate
EU	European Union
FCB	Formulated caffeinated beverage
FSSF	Formulated supplementary sports food
GMP	Good Manufacturing Practice
JECFA	Joint WHO/FAO Expert Committee on Food Additives
MPL	Maximum Permitted Level
NHMRC	National Health and Medical Research Council
NIP	Nutrition information panel
NIS	Nutrition information statement
Novel Food	See subsection 1.1.2—8 of the Code.
NRV	Nutrient reference value
Nutritive Substance	See subsection 1.1.2—12 of the Code.
OIA	Office of Impact Analysis
SD	Supporting Document
TGA	Therapeutic Goods Administration
TTMRA	Trans-Tasman Mutual Recognition Arrangement

1 Introduction

1.1 The Proposal

On 12 December 2020, Food Standards Australia New Zealand (FSANZ) raised this proposal to assess whether additional measures are required for caffeine in the Australian and New Zealand food supply in order to protect public health and safety.

The scope of the proposal includes:

- the addition of caffeine to Formulated Supplementary Sports Foods (FSSF) and other foods in the general food supply, and
- the extent of the risk posed to vulnerable sub-populations (e.g. children, adolescents, pregnant and lactating women) by caffeine in those foods and whether and how any such risk should best be managed.

1.2 Reasons for preparing the Proposal

Proposal P1056 was prepared following consideration of Urgent Proposal P1054 – Pure and highly concentrated caffeine products (P1054). P1054 was declared as an Urgent Proposal under section 95 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

P1054 was prepared to prohibit the retail sale of pure and highly concentrated caffeine products due to an unacceptably high risk for consumers and a need to act quickly to protect public health and safety.

In December 2019, for the reasons detailed in the P1054 Final Consideration Report (FSANZ 2020), the FSANZ Board approved a variation to the Australia New Zealand Food Standards Code (the Code) to prohibit the retail sale of pure and highly concentrated caffeine products.

The approved variation imposed a prohibition on a food for retail sale, unless expressly permitted by the Code, being a food in which caffeine is present in a concentration of:

- 1% or more of the food if that food is a liquid
- 5% or more of the food if that food is a solid or semi-solid food.

The approved variation prepared under P1054 took effect on 12 December 2019 in Australia and on 3 February 2020 in New Zealand.

The FSANZ Act required FSANZ to assess and then call for public submissions on the approved variation prepared under P1054. FSANZ assessed the approved variation in accordance with section 99 of the FSANZ Act and called for public submissions on 28 July 2020.

Section 101 of the FSANZ Act required FSANZ, after the public submission period and after taking into account all submissions made in that period, to do one of the following:

(a) reaffirm its decision to approve the P1054 variation, or
(b) prepare a proposal for the further variation of the Code as amended by that variation.

For the reasons stated in the P1054 'Amendment of the approved variation' report (FSANZ 2020), FSANZ decided to prepare a further proposal under the FSANZ Act. The P1054 report stated that the proposal would *consider whether additional measures are required in relation to caffeine in the Australian and New Zealand food supply in order to protect public health and safety; in particular:*

- *caffeine in sports food, which may consider a maximum limit on caffeine for foods in the general food supply; and*
- *the extent of the risk posed to sensitive subpopulations and whether and how any such risk should best be managed.*

P1056 is that proposal. The approved variation prepared under P1054 will remain unchanged and in force unless amended or repealed as a result of and at the completion of P1056. This ensures ongoing protection of consumers from pure and highly concentrated caffeinated products pending the outcome of P1056.

1.2.1 Formulated supplementary sports foods (FSSF)

The Code's regulation of FSSF is currently being reviewed by FSANZ through Proposal P1010 – Formulated Supplementary Sports Foods. The second recommendation of a report prepared by FSANZ for food ministers on pure and highly concentrated caffeine products (FSANZ 2019) was that:

> *FSANZ consider developing a maximum limit of caffeine in foods, based on the outcomes of the current review of Standard 2.9.4 – Formulated Supplementary Sports Foods. This work could be expedited, or the caffeine component could be separately progressed pending resources.*

This recommendation was accepted by food ministers. On this basis, FSANZ considered it prudent to consider the issue of caffeine in FSSF under the auspices of P1056 rather than P1010, to expedite any risk management measures.

1.3 Procedure for assessment

The proposal is being assessed under the Major Procedure as set out in the FSANZ Act. The Major Procedure requires two statutory rounds of public consultation.

The 1st Call for Submissions (CFS), released on 19 December 2022, sought feedback from interested parties on FSANZ's assessment and preliminary conclusion about whether to prepare a variation to the Code. It also included FSANZ's preferred approach.

After considering the submissions received in response to the 1st CFS, FSANZ decided to prepare a proposed draft variation (Attachment A). This 2nd CFS seeks feedback on the draft variation and the assessment and regulatory approach on which it is based.

Submissions received in response to this 2nd CFS will inform FSANZ's decision on whether to approve, amend or reject the proposed draft variation. If approved by FSANZ, the draft variation will be referred to the Food Ministers' Meeting (FMM) for consideration and endorsement.

1.4 Australia and New Zealand food regulations

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements relevant to this proposal are summarised below.

1.4.1 The Code

1.4.1.1 Addition of caffeine to food

The Code does not expressly prohibit the addition of caffeine to food or the presence of caffeine in food for purposes other than as 'a food additive', 'a processing aid', 'a novel food' or 'a nutritive substance'. The Code's general prohibitions on the use of substances as food additives, processing aids, novel foods and nutritive substances, unless expressly permitted, prevent the addition or use of caffeine in food in specific circumstances or for specific purposes only, as outlined in *sections 1.4.1.2 to 1.4.1.8 below.*

1.4.1.2 Processing aids

Paragraph 1.1.1—10(6)(c) of the Code provides that food for sale cannot contain, as an

ingredient or component, a substance *used as a processing aid* unless that substance's use as a processing aid is expressly permitted by the Code. There is no permission for the use of caffeine as a processing aid in the Code.

1.4.1.3 Food additives

Paragraph 1.1.1—10(6)(a) provides that food for sale cannot contain, as an ingredient or component, a substance *used as a food additive* unless that substance's use as a food additive is expressly permitted by the Code. Caffeine is specifically permitted to be used as a food additive in cola-type drinks only, with the technological purpose of a flavouring substance, as outlined below.

Section 1.1.2—11 defines the expression 'used as a food additive'. Subsection 1.1.2—11(1) provides that a substance is *used as a food additive* in relation to a food if both of the following conditions are met: the substance is added to the food to perform one or more technological functions listed in Schedule 14; and the substance is identified in subsection 1.1.2—11(2) – this includes (among other things) a substance identified in the table to section S15—5 as a permitted food additive. Section 1.3.1—3 details when substances are permitted to be used as food additives in food. Schedule 14 lists the permitted technological purposes of food additives. The table in section S14—2 provides that use as a flavouring is a permitted purpose.

The specific food additive permissions for different categories of foods are listed in the table to section S15—5. Caffeine is listed in that table as a permitted food additive for cola-type drinks, in food class 14.1.3.0.2, up to a maximum permitted level (MPL) of 145 mg/kg.

Schedule 16 sets out the types of substances that may be used as food additives in any processed food at Good Manufacturing Practice (GMP)[2] levels. The entry for 'Permitted flavouring substances' in tables to S16—2 specifically excludes caffeine. Therefore, any food categories in the table to section S15—5 allowing 'additives at GMP' or 'Permitted flavouring substances' are not permitted to contain caffeine within any flavouring preparation added to these food categories.

1.4.1.4 Nutritive substances

Paragraph 1.1.1—10(6)(b) requires that, unless expressly permitted, a food for sale must not have as an ingredient or component a substance that is *used as a nutritive substance* (as defined in section 1.1.2—12). There are no express permissions in the Code for caffeine to be used as a nutritive substance.

1.4.1.5 Novel foods

There is the potential for plants or extracts of plants that contain caffeine to be novel foods as defined in section 1.1.2—8 of the Code.

Novel foods are prohibited from being sold as a food offered for retail sale or as an ingredient or component in a food offered for retail sale unless expressly permitted by the Code (subsection 1.1.1—10(5)(b) and (6)(f)). There are no such express permissions in the Code

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[2] Section 1.1.2—2 of the Code defines **GMP** or **Good Manufacturing Practice** as:

With respect to the addition of substances used as food additives and substances used as processing aids to food, means the practice of:

(a) limiting the amount of a substance that is added to food to the lowest possible level necessary to accomplish its desired effect; and
(b) to the extent reasonably possible, reducing the amount of the substance or its derivatives that:
    (i) remains as a *component of the food as a result of its use in the manufacture, processing or packaging; and
    (ii) is not intended to accomplish any physical or other technical effect in the food itself;
(c) preparing and handling the substance in the same way as a food ingredient.

for novel foods containing caffeine.

1.4.1.6 Formulated caffeinated beverages

Formulated caffeinated beverages (FCBs) are regulated by Standard 2.6.4. FCBs must contain, amongst other things, no less than 145 mg/L and no more than 320 mg/L of caffeine in total.

1.4.1.7 Labelling requirements relating to caffeine

Subsection 1.2.4—7(6) requires that if caffeine is added to a food for sale, whether as a flavouring substance or otherwise, it must be listed in the statement of ingredients as 'caffeine'. This requirement applies to food for retail sale required to bear a label under section 1.2.1—6 and paragraph 1.2.1—8(1)(e).

Sections 1.2.3—2 and S9—2 require advisory statements indicating that the food contains caffeine for the following foods:

- a food *that* contains guarana or extracts of guarana
- a cola *beverage* that contains added caffeine
- a food *that* contains a cola beverage that also contains added caffeine as an ingredient.

For foods for retail sale that are required to bear a label, the advisory statement must be on the label of the food under section 1.2.1—6 and paragraph 1.2.1—8(1)(d). For foods for retail sale exempt from the requirement to bear a label, the advisory statement must be displayed in connection with the display of the food or provided to the purchaser upon request under subsection 1.2.1—9(6) and paragraph 1.2.1—9(7)(b).

Subsection 1.2.1—6(1) and paragraph 1.2.1—8(1)(v) set out the requirements for the labelling of FCBs for retail sale that are required to bear a label. The specific provisions for the labelling of FCBs are in section 2.6.4—5. Under these requirements, FCBs must be labelled with the average quantity, per serving size and per 100 mL of caffeine, expressed in milligrams. This may be adjacent to or follow a nutrition information panel (NIP) on the label but must not be set out in the NIP. An example format is provided in section S12—5.

Under subsection 2.6.4—5(3), FCBs must also be labelled with advisory statements to the effect that:

(a) the food contains caffeine; and
(b) the food is not recommended for:
    (i) children; or
    (ii) pregnant or lactating women; or
    (iii) individuals sensitive to caffeine; and
(c) if the food contains a 'listed substance'[3]—no more than a one-day quantity should be consumed per day. Caffeine is not a 'listed substance'.

If the FCB is not required to bear a label, these advisory statements must be displayed in connection with the display of the food or provided to the purchaser upon request (subsection 1.2.1—9(6) and paragraph 1.2.1—9(7)(g)).

1.4.1.8 Prohibition of pure and highly concentrated caffeine products

Paragraph 1.1.1—10(5)(g) of the Code provides that, unless expressly permitted by the Code, a food for retail sale cannot be a food that contains caffeine in a concentration of:

- 5% or *more* of the food for sale if that food is a solid or semi-solid food; or

[3] A *listed substance* means a substance listed in Column 1 of the table in section S28—2 of the Code. The list includes for example, thiamine and riboflavin.

- 1% or *more* of the food for sale if that food is a liquid.

1.4.2 Therapeutic Goods Administration

Regulation of foods and medicines falls under separate legislative frameworks commensurate with the intended use and potential risks that those products pose to public health and safety. In Australia, the Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Aged Care and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products. In contrast, FSANZ is responsible for developing standards in the Code that regulate food, under the FSANZ Act.

On 30 November 2020, the TGA created a legislative instrument under section 7 of the *Therapeutic Goods Act 1989* (TG Act) to help protect Australian consumers from the unsafe use of certain sports supplements. Under the TG Act, some sports supplements containing caffeine are declared to be a therapeutic good. This depends on a number of factors, including the daily dose of caffeine. As a result, caffeine containing sports foods, which meet the requirements of section 7 of the TG Act are now 'therapeutic goods' for the purposes of the TG Act. This means that these products are not regulated as 'a food', and the FSANZ Act, Australian and New Zealand food laws and the Code do not apply to them. For further background, refer to section 2.2 of the Amendment Report for P1054 – Pure and highly concentrated caffeine products (FSANZ 2020) and information on the TGA website.[4]

Standard 2.9.4 of the Code will continue to regulate foods sold as FSSF.

The Poisons Standard

The Poisons Standard exempts nearly all food from being a poison. Advice to FSANZ is exemptions in the Poisons Standard mean any restrictions imposed as a result of 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 TG Act).

When caffeine is not a food but is for internal therapeutic use, caffeine is a substance that is scheduled in the Therapeutic Goods (Poisons Standard – June 2024) Instrument 2024[5] (also cited as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)).

Caffeine used for internal therapeutic use, has been placed in Schedule 4 (prescription only medicines) of the Poisons Standard except:

a) in divided preparations when labelled with a maximum recommended daily dose of no greater than 600 mg of total caffeine; or

b) in undivided preparations with a concentration of 5% or less or caffeine and when labelled with a maximum daily dose of no greater than 600 mg of total caffeine.

Caffeine for all other uses has been specified as a Schedule 6 poison, except when included in Schedule 4, in preparations for external use, or in other preparations with a concentration of less than 5% of caffeine[6].

[4] Regulation of sport supplements in Australia: information for importers and sellers | Therapeutic Goods Administration (TGA)
[5] Federal Register of Legislation - Therapeutic Goods (Poisons Standard—June 2024) Instrument 2024
[6] 2.1 Caffeine | Therapeutic Goods Administration (TGA)

Schedule 6[7] 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.

1.4.3 Food Imported into Australia from New Zealand

The Trans-Tasman Mutual Recognition Arrangement (TTMRA) provides that most food may be imported into Australia from New Zealand and sold in Australia provided it complies with the New Zealand food law.[8] Most foods are also exempt from inspection under the Imported Food Control Act. New Zealand food law includes the *New Zealand Food (Supplemented Food) Standard 2016*.

Clause 1.9 of the *New Zealand Food (Supplemented Food) Standard 2016*[9] permits caffeine to be added to a supplemented food for any purpose other than as a food additive, as long as the label includes: (a) an advisory statement to the effect that the food contains caffeine and is not recommended for children, pregnant or lactating women, or individuals sensitive to caffeine; and (b) the average quantity of caffeine per serve and the average quantity of caffeine per 100 mL or 100 g. There are no prescribed maximum permitted levels for caffeine under the *New Zealand Food (Supplemented Food) Standard 2016.*

There is a general requirement around safe daily consumption which could apply to a supplemented food containing caffeine, or any other substance. 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 1.4 of the *New Zealand Food (Supplemented Food) Standard 2016* lists certain standards of the Code that do not apply to supplemented food, and the standards of the Code that apply as modified. Subsection 1.4(3)(b) states that other parts of the Code that ordinarily apply in New Zealand continue to apply to the supplemented food without modification. This includes paragraph 1.1.1—10(5)(g) of the Code, which currently sets maximum limits for the concentration of caffeine in food.

1.4.4 Regulation of caffeine internationally

FSANZ prepared a summary regarding the regulation of caffeine internationally, under P1054 (Appendix A – Final Consideration Report (FSANZ 2019)).

Pure and highly concentrated caffeine food products

The US FDA has issued guidance stating its position that the retail sale of certain pure and highly concentrated caffeine food products is prohibited under US food law because of the significant public health and safety risks they pose (USFDA 2018).

In September 2024, the UK Food Standards Agency and Food Standards Scotland issued guidance on caffeine in supplements, after a case in the UK where a person died after miscalculating the amount of caffeine powder he was meant to use.[10] Pure caffeine powder is regarded as a food supplement (not a food) in the United Kingdom.

Caffeine as flavouring

When added to food as an ingredient, caffeine is usually regulated as a food additive (flavouring).

The U.S. Code of Federal Regulations (CFR) enforced by the US Food and Drug Administration (US FDA) has a specific permission for caffeine as a Generally Recognised

[7] Understanding storage requirements for Schedule 6 and Schedule 7 chemicals in retail settings | Therapeutic Goods Administration (TGA)
[8] Importing food from New Zealand - DAFF (agriculture.gov.au)
[9] *New Zealand Supplemented Food Standard 2016*
[10] FSA and FSS issue guidance on caffeine in food supplements | Food Standards Agency

as Safe (GRAS) substance that can be added to cola-type drinks at a level up to 0.02% (200 mg/kg(L)) (USFDA 2020)). The US Food Chemicals Codex specification for caffeine lists its function as a flavouring agent.

The European Union permits caffeine as a flavouring substance under EU regulation 2018/1482 (European Commission 2018), with permissions listed in the Community List of Flavourings[11]. The specific permissions for caffeine addition to food as a flavouring are as follows:

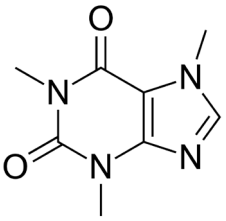
- non-alcoholic beverages (150 mg/kg).
- dairy products and analogues, and edible ices (70 mg/kg)
- confectionery (100 mg/kg)
- edible ices (70 mg/kg).

The levels of use of caffeine as a flavouring in cola-type drinks are therefore similar in Australia and New Zealand, the US and the EU (with a MPL of 145 mg/kg under the Code, compared to 200 mg/kg in the US and 150 mg/kg in Europe).

1.5 Chemical characterisation of caffeine

The chemical and physical properties of caffeine are summarised in table 1 below. Food Chemicals Codex has published a specification for caffeine (Food Chemicals Codex 2018).

Table 1: Chemical and physical properties of caffeine

Common name	Caffeine
Chemical name	1,3,7-Trimethylxanthine
Alternative names	Guaranine Methyltheobromine Thein(e)
IUPAC name	1,3,7-trimethylpurine-2,6-dione
Molecular formula (anhydrous)	$C_8H_{10}N_4O_2$
Molecular weight (anhydrous)	194.19 g mol^{-1}
CAS number (anhydrous)	58-08-2
Chemical structure	
Description	White powder or white glistening needles, odourless, with a bitter taste
Melting point (°C) (dried, 80°C 4 hrs)	235-238

Sources of caffeine

Caffeine (1,3,7-trimethylxanthine) is a naturally occurring alkaloid that is found in the leaves, seeds, or fruits of more than 60 plant species worldwide. The best known of these are coffee and cocoa beans, tea leaves, guarana and the kola nut. Caffeine can also be chemically synthesized.

When caffeine is added to foods as a permitted substance, a food manufacturer could use caffeine from a plant source (e.g., from coffee beans or tea leaf waste) or the chemically synthesized form. There is no chemical difference.

[11] Food and Feed Information Portal Database | FIP

However, some plants or plant extracts that contain caffeine may also contain other plant components or substances, which may or may not be suitable for food use. The safety of caffeine-containing plants or extracts may therefore be independent of the caffeine component.

In such cases, plants or extracts containing caffeine may meet the definition of a novel food and therefore require a pre-market assessment of public health and safety (under the FSANZ application process) before being permitted to be added to food or sold for retail sale as a food. Where a plant or plant extract source of caffeine is an unapproved novel food, that plant or extract is not a permitted food, and therefore, not an authorised source of caffeine.

Whether or not a particular caffeine-containing plant source of caffeine meets the definition of a novel food is not within the scope of this proposal.

2 Summary of issues raised in submissions

FSANZ released a 1st CFS on 19 December 2022 seeking submissions on FSANZ's assessment of P1056, the preliminary conclusions of that assessment, and FSANZ's preferred approach based on those conclusions.

FSANZ's assessment considered three regulatory options:

(1) the status quo;
(2) the status quo combined with non-regulatory measures (such as consumer education); or
(3) amendment of the Code plus non regulatory measures.

FSANZ's preferred approach was Option 3 which proposed:

- to explicitly permit in FSSF, total caffeine up to 200 mg in a one-day quantity
- an express prohibition on the addition of caffeine to other foods for retail sale, other than those that have a specific permission i.e. cola-type drinks and FCBs
- the removal of the P1054 variation.

The 1st CFS was released for an eight-week public consultation period between 19 December 2022 and 13 February 2023. FSANZ received a total of 22 submissions (10 government, 10 industry and two public health) (tables A-G, Appendix 1).

All submissions were published on the FSANZ website. Two submissions were received as confidential and could not be published in full.

Submitters to the 1st CFS are listed in Table 1 of Appendix 1. A summary of the main issues raised in the submissions and FSANZ's responses are set out in the following sections. Detailed responses to all issues raised in submissions are provided in Appendix 1.

2.1 Risk assessment

2.1.1 Hazard assessment

The key conclusions of the FSANZ hazard assessment for caffeine set out in the 1st CFS were:

- Single intakes of caffeine of up to 210 mg for adults (approximately 3 mg/kg body weight (bw)) were not generally associated with adverse effects. Above that dose, caffeine intake is associated with an increase in blood pressure, plasma catecholamines and anxiety.
- Chronic, moderate consumption of caffeine at up to 400 mg/day (5.7 mg/kg bw/day) was not associated with significant adverse effects in the general adult population. This is based on extensive epidemiological evidence, including systematic reviews and meta-analyses.

- Caffeine intake of pregnant women should be limited to 200 mg caffeine/day or less because levels above this limit may increase the risk of miscarriage, stillbirth, preterm delivery, low birthweight and small for gestational age infants.
- The rate of clearance of caffeine in adolescents is comparable to that of adults, so caffeine intake up to 5.7 mg/kg bw/day, the bodyweight-adjusted equivalent of the recommended maximum for adults, is likely to be safe for this age group.
- Safe levels of single intake of caffeine for children up to 3.0 mg/kg bw/day[12] have been extrapolated from adults based on bodyweight. Some disruption of sleep may occur at intakes below this level (see SD 1).
- Infants and pre-schoolers are at risk of life-threatening caffeine poisoning from acute exposure due to their low bodyweights. Data from poison centres in Australia and New Zealand indicate that infants and toddlers are over-represented among calls related to acute caffeine exposure.

2.1.1.1 Submissions

In general, submissions supported the safe levels of caffeine for adults, pregnant and lactating women, adolescents and children identified by FSANZ at the 1st CFS.

2.1.1.2 FSANZ response

No scientific evidence was provided by submitters that would warrant a change to FSANZ's conclusions about safe levels of caffeine consumption in these population subgroups.

2.1.2 Dietary intake assessment

A dietary intake assessment was conducted to estimate usual intakes of caffeine from foods and beverages for Australian and New Zealand population groups and determine if intakes exceeded recommended maximum levels (SD2 in the 1st CFS).

The assessment indicated that no or few children and adolescents had a usual caffeine intake that exceeded the recommended maximum levels (3 mg/kg /bw/day and 5.7 mg/kg bw/day respectively), but up to 6% of Australian adults (aged 20 years and above) and 2% of New Zealand adults (aged 15 years and above) exceeded the recommended maximum levels (400 mg/day for an adult).

Less than 5% of adolescent and adult respondents to the Australian and New Zealand national nutrition surveys reported consuming a sports food or beverage, which contributed up to 6% of total caffeine intake for these consumers.

Only a small proportion of respondents to the 2011-12 Australian National Nutrition and Physical Activity Survey reported consuming a dietary supplement containing caffeine (4%), and caffeine intakes from dietary supplements were minimal in comparison to the usual intakes from food.

The highest contributing food group to day one caffeine intakes was non-alcoholic beverages for all population groups assessed. Within this group, coffee, tea and soft drinks were major (>5%) contributors of caffeine for different population groups.

2.1.2.1 Submissions

Some submitters noted due to the age of the most recent Australian (2011-12) and New Zealand (2008-09) National Nutrition Survey data used in the dietary intake assessment, data may not reflect current consumption of caffeinated food and beverages.

[12] Expressed per kg bodyweight because of the rapid growth of children. Assuming body weights of 13 kg for a 1-3 year old and 22kg for a 4-8 year old (NHMRC, 2006), the respective approximate safe intakes for children would be 39 mg/day and 66 mg/day.

2.1.2.2 FSANZ response

FSANZ acknowledges the limitation of the dietary intake assessment in the consumption data used in the assessment do not reflect changes in the consumption of caffeinated food and beverages over the past 12-15 years. Given this limitation, FSANZ has also considered additional lines of evidence on recent patterns of consumption of sports foods and beverages in the social science assessment set out in section 2.1.3 below. Recent apparent consumption data published by the Australian Bureau of Statistics (ABS)[13] also support FSANZ's conclusions and were included in SD2 after consideration of the submissions.

2.1.3 Social Science assessment

The social science assessment involved a systematic review of the literature on the nature and extent of the risks (if any) associated with consumer understanding and/or behaviour regarding caffeine in both general foods and sports foods that are currently available in the Australian and New Zealand food supply. It had a specific focus on the sub-populations of children, adolescents, athletes, and pregnant and/or lactating women as well as the broader population.

The findings complement and extend the findings of FSANZ's dietary intake assessment, particularly for the subpopulation of pregnant women, which was not able to be directly examined. Although not all studies in the social science review utilised nationally representative samples comparable to those employed in the dietary exposure assessment, some provided more recent consumption information than that available in the National Nutrition Surveys.

The key findings of the social science review were:

- There is very little evidence that Australian or New Zealand children are regularly consuming caffeine in excess of 3 mg/kg bw/day. While there is some evidence that younger adolescents may be unaware of the caffeine content of energy drinks, there is little substantial evidence that adolescents are regularly consuming caffeine in excess of 5.7 mg/kg bw/day.
- A subset of consumers among pregnant women (typically less than 15%) are regularly exceeding the recommended maximum daily limit of caffeine. Coffee was the major contributor to overconsumption. While the majority of pregnant women are consuming within the recommended limits, it is not clear whether they were aware of, or had received advice consistent with, the 200 mg/day caffeine limit.
- The prevalence of caffeine intake in excess of 400 mg/day may differ across different sub-populations of the general adult population. Two studies found that between 14 and 17% of the population may be regularly exceeding safe levels. Two other studies found that a proportion of university students, and nurse and midwife shift workers were amongst those who typically consumed caffeine in excess of 400 mg/day. Coffee was the major contributor to overconsumption. There was insufficient information available to make an assessment about the impact of consumer knowledge on caffeine consumption behaviour.
- Up to 19.5% of adults, including those both active and sedentary, may consume sports foods. Sports foods were not found to be a major contributor to daily caffeine intake in children, adolescents or a sample of university students. No studies directly examined the contribution of sports food products to total caffeine intake in athletes, pregnant women or the general population.
- Evidence suggests that some athletes, military personnel and individuals from the general population are consuming multiple types of sports food products, sometimes within the same day (i.e. stacking), although it is not clear whether these products contain

[13] Apparent consumption data are the amount of food and non-alcoholic beverages purchased from retail outlets, including major supermarkets, convenience stores, butchers, seafood shops, bakeries, delis and fresh food markets (ABS 2024).

caffeine. Stacking caffeinated sports food products may put consumers at risk of inadvertently exceeding the recommended maximum daily limit if they are unaware of those limits or of the amount of caffeine in sports food products. However, there was no information available regarding consumer awareness of the amounts of caffeine in sports foods, nor understanding of the recommended daily maximum limit of caffeine.

2.1.3.1 Submissions

A submitter suggested that there was a lack of nationally representative data on overconsumption of caffeine and sub population groups.

2.1.3.2 FSANZ response

FSANZ notes the submitter did not provide any new scientific evidence on caffeine consumption that would warrant a change to FSANZ's assessment.

Minor clarifying changes in response to submissions have been included in an updated risk assessment (SD3) to this report and are outlined in Appendix 1.

2.1.4 Risk assessment conclusions

The risk assessment identified safe levels of caffeine intake for adults, pregnant women, adolescents and children. Submitters generally agreed with the safe levels of caffeine established by FSANZ.

The dietary exposure assessment concluded no or few children and adolescents had a usual caffeine intake that exceeded safe consumption levels, however a small proportion of adults did exceed the safe levels of daily intake. Coffee, tea and soft drinks were major contributors of caffeine for different population groups.

A limitation of the dietary exposure assessment was that consumer access to caffeinated goods and consumption patterns may have changed since the completion of the National Nutrition Surveys used in the dietary intake assessment.

For that reason, FSANZ considered additional lines of evidence on recent patterns of consumption of sports foods and beverages as part of a social science assessment of the risks associated with consumer understanding and/or behaviour regarding caffeine in both general foods and sports foods that are currently available in the Australian and New Zealand food supply.

The assessment found a proportion of the Australian and New Zealand population are likely to exceed safe levels including a proportion of pregnant women and 14% to 17% of non-pregnant adults. In addition, some sub-groups such as shift workers and athletes may be more likely to exceed safe levels.

P1054 identified there is also a risk of acute poisoning from inadvertent consumption of concentrated caffeine products. These types of products pose higher risks to infants and children due to the low body weight of infants and children relative to adults. Further, the cost and benefits assessment (see section 2.4.1.1 below and SD5) also identified that caffeine is present, sometimes at high concentrations in sports foods, which are being increasingly consumed in the community. It was also observed that some products on the market exceed the safe level for a single dose of caffeine.

2.2 Risk management

At the 1st CFS, FSANZ undertook an analysis of various risk management options. The preferred option was Option 3 which proposed:

- an express prohibition on the addition of caffeine to other foods for retail sale, other than those that have a specific permission i.e., cola-type drinks and FCBs

- to explicitly permit in FSSF, total caffeine up to 200 mg in a one-day quantity
- the removal of the P1054 variation.

2.2.1 Express prohibition

For the reasons stated in the 1st CFS, FSANZ proposed amending the Code to prohibit food for retail sale from containing added caffeine as an ingredient or component, unless expressly permitted by the Code (i.e., currently FCBs and cola-type drinks and, if approved, FSSF).

The express prohibition on the addition of caffeine to foods for retail sale unless explicitly permitted would reduce the likelihood of overconsumption of caffeine, in particular highly caffeinated products, and prevent these products becoming more widespread in the general food supply. This would be of benefit to public health and safety (refer to section 2.2 of this report).

This would not affect the ability to sell foods that contain caffeine by natural occurrence, for example coffee, tea and chocolate (unless the novel foods provisions apply as mentioned in section 1.4.1.5 above). The current regulation of caffeine in cola-type drinks and FCBs would remain unchanged.

2.2.1.1 Submitter comments

The proposed approach for an express prohibition on the addition of caffeine to all foods for retail sale unless expressly permitted was largely supported by submitters, citing increased regulatory clarity regarding the addition of caffeine to foods, benefits to public health and safety and alignment with the Regulatory Management of Caffeine in the Food Supply Policy Guideline (2014).

2.2.1.2 FSANZ Response

Following consideration of submitter comments and for the reasons set out in this report, FSANZ is proposing the following prohibitions for caffeine in the Code:

- inclusion of an express prohibition on the retail sale of caffeine as a food
- inclusion of an express prohibition on the addition of caffeine as an ingredient or component, to foods for retail sale, other than those that have a specific permission.

The aim is to reduce the risk of over-consumption by sub-populations including pregnant women, children and athletes identified in section 2.2 of this report.

The proposed prohibition would provide certainty for food manufacturers and enforcement agencies on the retail sale of caffeine and the addition of caffeine to foods for retail sale.

FSANZ considers that the current permissions to add caffeine to cola-type drinks and FCBs and the proposed new permission for FSSFs (section 2.2.3), will provide consumers with continued safe and reasonable access to products with added caffeine, post imposition of the prohibition. Should food businesses wish to add caffeine to foods where there is no specific permission, or to amend existing permissions, an application to amend the Code could be made to FSANZ.

This approach also maintains, by way of the proposed prohibition, the restrictions of the retail sale of pure and highly caffeinated products that were identified by P1054 as being unsafe (see section 2.2.2 below). This approach is maintained due to the unacceptably high risk to consumers posed by such products.

Paragraphs 1.1.1—10(5)(g) and 1.1.1—10(6)(k) of the draft variation prepared by FSANZ reflect the proposed approach (see Attachment A).

2.2.2 Removal of the P1054 variation

Section 3.2.2 of the 1st CFS proposed the removal of paragraph 1.1.1—10(5)(g) of the Code. P1054 added that paragraph to the Code to prohibit the retail sale of a food containing caffeine in a concentration of:

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

Removal of the paragraph and the above prohibition was proposed in the 1st CFS because of the following:

- The proposed prohibition on the addition of caffeine to foods for retail sale unless expressly permitted (e.g., as for FCBs, cola-type drinks and, if approved, FSSF) would capture the highly concentrated caffeinated products that were considered to pose a risk under P1054
- Some of the highly concentrated caffeinated products that were considered to pose a risk under P1054 are regulated as therapeutic goods (see section 1.4.2 above).

The above mean that the 1 and 5% restrictions would no longer be required in paragraph 1.1.1—10(5)(g) of the Code.

2.2.2.1 Submitter Comments

Submitter comments on the removal of the P1054 variation were mixed.

Some submitters supported the removal, noting that the limits introduced by the TGA would address risks from pure and highly concentrated caffeine products that are not foods.

Other submitters, considered the 1 and 5% restrictions should remain in the Code so that products with a high concentration of caffeine could not be a food for retail sale i.e., sold directly to consumers.

2.2.2.2 FSANZ Response

FSANZ maintains the view held in the 1st CFS that, if FSANZ's proposed approach is adopted, the separate general prohibition on pure and highly concentrated caffeinated products for retail sale would not be required. FSANZ's proposed approach would prohibit such products.

Paragraphs 1.1.1—10(5)(g) and 1.1.1—10(6)(j) of the draft variation prepared by FSANZ therefore reflect this proposed approach (see Attachment A).

FSANZ has also proposed a specific approach for managing caffeine concentrations in FSSF including one day quantity permissions and concentration limits and packaging requirements for small volume FSSF, liquids and powders (see section 2.2.4).

2.2.3 200 mg one-day quantity permission in Standard 2.9.4

There is currently no express permission in the Code for the addition of caffeine to FSSF.

For the reasons stated in the 1st CFS, FSANZ proposed to amend the Code to include an express permission for FSSF to contain a maximum of 200 mg of caffeine in a one-day quantity in conjunction with labelling requirements (see section 3.2.1.6 of the 1st CFS) (FSANZ 2022).

The proposed limit of 200 mg of caffeine in a one-day quantity accounts for the mean caffeine intake from all other food sources (e.g., caffeinated beverages), so that total intake is not expected to exceed 400 mg/day (see section 3.2.1.6 of the 1st CFS) (FSANZ 2022). This assumes that consumers are using FSSF in accordance with the directions on the label.

2.2.3.1 Submitter comments

Submitters generally supported the proposal to permit up to a maximum of 200 mg of caffeine in a one-day quantity in FSSF. Submitters commented that the proposed approach was supported by the ergogenic benefit and safety evidence, provided clarity for industry and enforcement and would reduce the risk of overconsumption of caffeine.

One submitter, while supportive of the proposed approach, expressed concern that sports science about caffeine is poor, noting the assessment finding of a low level of certainty from the evidence that caffeine is beneficial for athletes in relation to time trials.

Only one industry submitter did not support the approach in its entirety, stating that it did not allow for future product development needs. This submitter also suggested that FSSF should only be sold to adults and should be able to contain up to 600 mg caffeine, the level that the TGA considers to be a therapeutic dose.

Submitters also commented that the proposed approach may not appropriately protect adolescents from acute caffeine-related safety risks noting that the one-day quantity would exceed the acute safe level for adolescents. Submitters asked that further consideration be given to adolescents in relation to the Ministerial Policy Guideline on the Regulatory Management of Caffeine in the Food Supply.

Submitter comments are addressed in detail in table D, Appendix 1 to this report.

2.2.3.2 FSANZ response

After consideration of submissions, FSANZ is proposing the same approach as in the 1st CFS. That is, to amend the Code to provide an express permission for FSSF to contain caffeine up to a maximum of 200 mg per one-day quantity. The proposed requirement is included in section 2.9.4—3(2)(b) in the proposed draft variation.

A one-day quantity is the amount of FSSF which is to be consumed in one day in accordance with directions specified in the label. The proposed maximum 200 mg one-day quantity of caffeine in FSSF was based on the FSANZ safety assessment indicating that a single acute dose of up to 210 mg and a daily amount of up to 400 mg are not associated with adverse effects in non-pregnant adults or adolescents (refer to SD1). The minor differences in body weight between adolescents and adults are unlikely to be significant.

FSANZ's assessment found that caffeine has a small beneficial ergogenic effect within the range of 1.25-3 mg/kg bw and 6 mg/kg bw (SD4 to the 1st CFS) (FSANZ 2022). In that respect, FSANZ's findings are consistent with the findings of peak international bodies (see Appendix 2).

The submitter did not provide any scientific information to support that 600 mg caffeine is a safe level for use in a FSSF. This level substantially exceeds the safe level established as a part of FSANZ's risk assessment and supported by the conclusions of other international assessments (SD1 to the 1st CFS) (FSANZ 2022). Further there are differences between the use of a substance in food and therapeutics, including a consideration of the:

- risks and benefits of the use of a substance;
- purpose for which a substance is to be used and the extent of use of a substance; and
- dosage, formulation, labelling, packaging and presentation of a substance.

Setting a maximum 200 mg one-day quantity of caffeine for FSSF in conjunction with labelling requirements is consistent with the specific policy principles. This approach is also consistent with the permissions for added substances already contained in Standard 2.9.4 – Formulated Supplementary Sports Foods. It recognises that FSSF are special purpose foods, being a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals.

2.2.4 Additional restrictions for the addition of caffeine to FSSF

The section above sets out that FSANZ proposes to amend the Code to include an express permission for FSSF to contain a maximum of 200 mg of caffeine in a one-day quantity in conjunction with labelling requirements.

Section 3.2.2 of the 1st CFS proposed the removal of paragraph 1.1.1—10(5)(g) of the Code. P1054 added that paragraph to the Code to prohibit the retail sale of a food containing caffeine in a concentration of:

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

At the 1st CFS FSANZ did not propose any specific limits on the concentration of caffeine in FSSF.

2.2.4.1 Submitter comments

While some submitters supported the removal of the paragraph 1.1. 1—10(5)(g) requirement (see section 2.2.2.1), several expressed concerns that a risk would remain for small volume FSSF that contain caffeine in the absence of concentration limits.

2.2.4.2 FSANZ response

In considering the proposed permission for the addition of caffeine to FSSF and removing the existing restrictions imposed by paragraph 1.1.1—10(5)(g), certain sports food products meeting the maximum one-day quantity could result in high intakes of caffeine because of the format in which they are presented to consumers. These products are (1) powders, (2) small volume solid and semi-solid FSSF (such as chewables and dissolvable strips) containing caffeine and (3) concentrated liquid FSSF containing caffeine.

Powders

P1054 concluded that a 5% maximum limit should be applied to all solid and semi solid foods containing caffeine due to these products being able to provide high amounts of caffeine in very low serving sizes that are potentially difficult to accurately measure with equipment available to most consumers (e.g. standard kitchen scales). P1054 also concluded that powders containing less than 5% caffeine are of lower risk as a person would have to consume several tablespoons of powder to lead to severe adverse health effects (FSANZ 2019b). These conclusions are applicable to FSSF in powdered form.

For the reasons stated in the 1st CFS (sections 3.1 and 3.2.2), FSANZ proposed the removal of the 5% maximum limit from paragraph 1.1.1—10(5)(g).

After considering submissions, reviewing the market scan (SD5), and reconsidering the risk posed by such products, FSANZ now proposes to retain the 5% maximum limit for FSSFs that are powders. The proposed requirement is included in the draft variation under section 2.9.4—3(3)(a) (Attachment A).

Chewables and dissolvable strips

For certain small volume, solid and semi-solid FSSF (e.g. chewables such as gummies, and dissolvable strips), FSANZ considers that applying the 5% concentration limit is not an appropriate risk management approach.

This is because these products may be sold in bulk packaging where either (1) the bulk packet may contain less than or equal to the 200 mg daily amount in each individual portion, but because they are lightweight, each portion could be greater than the 5% maximum limit or (2) each portion provides less than or equal to the one day maximum of 200 mg, but with a

total packet caffeine content of 4-5 g. Due to their size and high caffeine concentration, these products can be over-consumed and exceed the recommended safe levels of caffeine. Additionally, bulk packaging of products such as gummies poses significant risk of serious, even fatal poisoning in small children, since they can be mistaken for confectionery.

Proposal P1054 found that individually divided and packaged small volume highly caffeinated sports food products have a different risk profile to multiple pieces in undivided packaging because the total caffeine exposure is likely to be limited by the form of packaging (FSANZ 2019b). For example, products such as lightweight caffeinated strips are typically portion controlled as single individually packaged serves; they are sold in small quantities per pack with instructions for use. Proposal P1054 concluded that chewables and gels are unlikely to pose a risk to health when presented for sale in portion-controlled serves per package (FSANZ 2020b).

Therefore, FSANZ proposes to require individual wrapping of all pieces within a bulk packet of caffeine-containing FSSF, when the pieces require no further preparation, and the bulk packet contains more than a total of 200 mg caffeine. The proposed approach to individual wrapping excludes powders containing multiple serves such as pre-workouts. Requiring individual wrapping of pieces within a bulk packet would address safety concerns regarding the over consumption of products such as caffeine-containing chewables, dissolvable strips and confectionery-like FSSF.

This approach recognises that some small volume solid or semi-solid FSSF are specifically formulated for a particular situation (e.g. long-distance running), are consistent with the definition of FSSF, and are intended to deliver a single dose of caffeine in one portion. The objective in requiring small volume caffeinated products to be individually wrapped is not to prohibit such products (which are not readily available to the general population) but to reduce the likelihood of consuming multiple pieces at one time and at levels at which the risk of serious adverse effects is increased.

The proposed requirement for individual wrapping of pieces of caffeine-containing FSSF within a bulk packet is included in the draft variation under section 2.9.4—12(2) (Attachment A). Gels, which are used similarly to chewables, are unlikely to pose the same risk as these are by nature already individually packaged. Appropriate forms and representation of FSSF (including chewables and gummies) will be further considered under proposal P1010 Review of Formulated Supplementary Sports Foods.

Concentrated liquid FSSF containing caffeine

In the Proposal P1054 Final Consideration Report (FSANZ 2019b), it was noted that concentrated caffeine solutions, which may be used to make energy drinks by some consumers, are of high risk and pose a significant health concern. While commercial energy drinks are not FSSF, other types of concentrated caffeine solutions may be categorised as FSSF to be used in consumer prepared food such as a protein shakes or as a standalone liquid, ready to drink product that contains caffeine.

Proposal P1054 considered that for concentrated caffeine solutions, a maximum permitted level of 1% w/v caffeine was required to protect public health and safety. This was based on the intended delivery of 100 mg of caffeine in a volume of 10 mL of a liquid product. The restriction to 1% concentration intends to manage the risk of inaccurately measuring out a product that is used in very small amounts.

Therefore, FSANZ proposes to restrict caffeine present in FSSF in a liquid form to less than 1% w/v caffeine. The requirement is included in the draft variation under section 2.9.4—3(3)(b) (see Attachment A).

2.2.5 Sources of caffeine

In the first CFS, section 1.4 discussed the addition of plant extracts and concentrated forms

of caffeine stating that:

- P1056 is considering the addition of caffeine to foods, where permitted, regardless of the source (i.e. synthetically produced or from a plant source such as guarana extract).
- When plants containing caffeine are prepared as food ingredients, they can be intentionally concentrated and standardised to a range of caffeine concentrations.
- Some plants containing caffeine, whether the whole plant or an extract from a plant source, may meet the definition of a novel food in the Code and require a pre-market assessment before they can be added to food irrespective of the purpose of addition to food.
- Whether or not a particular plant source of caffeine meets the definition of a novel food is not within the scope of this proposal.

2.2.5.1 Submitter comments

Submitter commentary was varied, with some submitters making suggestions on how to manage caffeine content in foods from caffeine-containing extracts. Some submitters suggested a total caffeine limit is applied to all foods. Others suggested an upper concentration limit for caffeine-containing extracts or defining caffeine in the Code in a way that included extracts.

2.2.5.2 FSANZ Response

FSANZ is not proposing to define and regulate caffeine-rich extracts as 'caffeine' or to apply a total caffeine limit to all foods. It is likely that a number of caffeine-rich plant extracts would be unapproved novel foods which, consistent with the current Code provisions, could not be used as an ingredient in a food for retail sale or be sold as a food for retail sale.

As noted in section 1.5 above, where caffeine is permitted to be added to a food under the Code, and a permitted plant source of caffeine is used in that food, the requirements for total caffeine content (whether expressed as a maximum level or a one-day quantity) would apply.

The proposed amendments in P1056 would not impact the sale of foods such as coffee, teas and chocolate that naturally contain caffeine. The compositional requirements for these foods are included in the Code in Standard 2.10.4 – Miscellaneous standards for other foods. Subsection 1.1.1—10(7) of the Code allows for the presence of caffeine by natural occurrence in a compliant food or ingredient.

Subsection 1.1.1—10(7) does not of itself, permit the retail sale of a caffeine-containing plant that is an unapproved novel food, nor does it permit the retail sale of a food that has a caffeine-containing plant that is an unapproved novel food as an ingredient. In this case, a premarket safety assessment would be required. The Advisory Committee on Novel Foods (ACNF) Record of Views contains committee recommendations regarding plant sources of caffeine[14].

A manufacturer's ability to buy or sell caffeine-containing ingredients wholesale for the production of a permitted caffeine-containing food will not be impacted, providing the ingredient complies with any other regulations with which it is required to comply when added to a food.

2.2.6 Labelling of formulated supplementary sports foods containing caffeine

The following sections outline the labelling related submitter comments and risk management measures proposed for FSSF.

[14] Novel food - Record of views formed in response to inquiries | Food Standards Australia New Zealand

2.2.7 Advisory statement ‘contains caffeine’

In the 1st CFS, for the reasons stated in the CFS, FSANZ proposed a requirement for an advisory statement using wording to the effect of ‘contains caffeine’ on the label of all FSSF containing caffeine, irrespective of the source or amount. For FSSF not required to bear a label under Standard 1.2.1, FSANZ proposed that the advisory statement would be required to be provided either in connection with the sale of the food or upon request, for example, on a sign or verbally if asked.

2.2.7.1 Submitter comments

Some submitters supported the proposed approach to require the advisory statement using wording to the effect of ‘contains caffeine’ on the label of all FSSF containing caffeine.

It was noted that there may be merit in mandating the actual words ‘contains caffeine’ for consistency across food labels.

2.2.7.2 FSANZ response

After consideration of submissions, FSANZ is proposing to maintain the approach for an advisory statement to the effect of ‘contains caffeine’ on FSSF containing added caffeine, as proposed in the 1st CFS and outlined above.

FSANZ is not proposing to prescribe the actual wording of the advisory statement, consistent with the current approach for advisory statements in Standards 1.2.1 and 1.2.3 of the Code. The proposed requirement would be included in the table in section S9—2 of Schedule 9 and relies on the existing requirement in subsection 1.2.3—2(1) for advisory statements in that table (see Attachment A).

The requirement would be consistent with the current requirement for an advisory statement on other foods with specific permission to contain added caffeine, such as cola-type beverages and FCBs.

Noting the risks associated with consumption of caffeine (refer to sections 2.2 and 2.2.1.2 above), it is proposed that consumers are alerted to the presence of caffeine via the advisory statement, irrespective of its source or the amount present, given they may not expect FSSF to contain caffeine. This is unlike tea or coffee for example, which are not required to be labelled with the advisory statement given consumers are more likely to be aware these products contain caffeine.

2.2.8 Declaration of amount of caffeine and one-day quantity

In the 1st CFS, FSANZ proposed a new requirement to declare the average quantity of caffeine present (from all ingredient sources) in any FSSF containing caffeine, irrespective of the source or amount. Caffeine content would need to be declared in mg, on a per serving and per unit quantity (100 g or 100 mL) basis, in the NIP, following the entry for sodium, where other biologically active substances are required to be declared, if any.

For products requiring reconstitution with water, the declaration would be for the product following reconstitution. This is consistent with the current requirement for NIPs in Standard 1.2.8 (section 1.2.8—11 of the Code).

Regarding the ‘one-day quantity’ (to not exceed 200 mg caffeine) outlined in section 2.2.3 above, under the current labelling requirements for directions stating the recommended amount and frequency of consumption of the food and a statement of recommended consumption in one day (section 2.9.4—4 of the Code), the instructions on a FSSF should not direct consumers to consume more than 200 mg per day of caffeine from that FSSF. FSANZ therefore did not propose any amendments to the existing labelling requirements for FSSF in the 1st CFS.

There are currently no requirements for these directions to be provided for FSSF not required to bear a label. In the 1st CFS FSANZ proposed to maintain this approach under this proposal but to consider it more broadly for all FSSF under Proposal P1010.

2.2.8.1 Submitter comments

There was support from submitters for the approach proposed in the 1st CFS, with no submitters opposing the approach.

2.2.8.2 FSANZ response

FSANZ is proposing to maintain the approach in the 1st CFS and as outlined above. The proposed requirement to declare the average quantity of caffeine in the NIP is included in section 2.9.4—11 in the proposed draft variation (Attachment A).

FSANZ considers it is appropriate to require the declaration of caffeine content in the NIP as this is consistent with the approach to declare biologically active substances in the panel if a nutrition content or health claim is made. It also allows for the prescribed format of the NIP to apply to the caffeine declaration for consistency across FSSF containing caffeine.

FSANZ considers the existing labelling requirements for directions for use would require the provision of appropriate information to advise consumers about safe caffeine intake from a FSSF. It would also enable enforcement of the proposed one-day quantity requirement when the proposed NIP entry is read in conjunction with the directions for use.

The proposed requirement to declare the average quantity of caffeine in the NIP would also assist with preventing consumers being misled from FSSF containing minimal or ineffective amounts of caffeine with respect to sports performance but labelled as containing caffeine (in accordance with the proposed advisory statement), as they will be informed about the quantity present.

The proposed requirement to declare the average quantity of caffeine in the NIP would mean that such a declaration is not a nutrition content claim (subsection 1.1.2—9(2) of the Code).

2.2.9 Other advisory and warning statements

FSSF are currently required to be labelled with the warning statement: *Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision.* The exact wording as prescribed in this statement is currently required to be on the label of all FSSF.

FCBs are required to be labelled with an advisory statement to the effect that the food is not recommended for children, pregnant or lactating women, or individuals sensitive to caffeine (see Standard 2.6.4 of the Code). This differs to the advisory statement currently required on FSSF, by the inclusion of lactating women and individuals sensitive to caffeine.

In the 1st CFS, FSANZ did not propose a warning or advisory statement for FSSF containing added caffeine specifically for lactating women or individuals sensitive to caffeine.

For lactating women, this was on the basis of there being very little information on the effects of maternal caffeine exposure via breastmilk on infants. It was considered that the proposed one-day quantity would limit exposure to caffeine in infants via breastmilk from consumption of FSSF containing caffeine by lactating women. The proposed labelling information about the presence and amount of caffeine and resources providing advice and information about caffeine intake when lactating also supported this approach.

2.2.9.1 Submitter comments

Although some submitters supported the proposed approach, some did not. In particular, public health and government representatives recommended additional statements for FSSF:

- to be the same as FCBs, to include 'while lactating and those sensitive to caffeine'
- to include adolescents, noting their lower body weight and that overseas authorities have concluded between 2.5 – 3 mg/kg of body weight per day is the recommended maximum level of no safety concern for adolescents (compared to 5.7 mg/kg of body weight per day concluded by FSANZ).

2.2.9.2 FSANZ response

Following consideration of submitter comments, FSANZ is now proposing to require a new warning statement for FSSF containing caffeine. The required wording for the warning statement would be the same as that for the existing warning statement for FSSF, with the addition of breastfeeding women. No amendments are proposed to the wording of the warning statement for FSSF that do not contain caffeine. This ensures that the existing warning, including reference to medical or dietetic supervision, continues to be required for all FSSF. The required warning statement for FSSF containing caffeine would be:

> *Not suitable for children under 15 years of age or pregnant or breastfeeding women: Should only be used under medical or dietetic supervision.*

As the wording of the warning statement is prescribed, i.e. the exact wording as required in the Code must be used on the label, FSANZ proposes 'breastfeeding' rather than 'lactating' is used, to assist with consumer understanding.

This approach takes into account concerns raised by submitters, evidence that a portion of caffeine circulating in the bloodstream enters breast milk, and that there is insufficient data to establish a health-based guidance value for breastfed infants for caffeine consumed via breastmilk.

FSANZ is not proposing to require warning or advisory statements referring to adolescents for FSSF containing caffeine. Children under 15 are already mentioned in the existing warning statement and FSANZ considers the existing and proposed risk management measures to be sufficient for this population (see section 2.2.3.2 above).

FSANZ is also not proposing to require additional warning or advisory statements referring to individuals sensitive to caffeine, for the same reasons as provided in the 1st CFS, i.e. the proposed labelling information about the presence and amount of caffeine and likely knowledge of this population group about caffeine consumption would be sufficient to manage risks.

2.2.10 Nutrition content and health claims

Nutrition content claims about FSSF are regulated by Standard 1.2.7 and Standard 2.9.4. By definition, they include claims about the presence or absence of a 'biologically active substance', which is defined as *a substance, other than a nutrient, with which health effects are associated.* Assuming caffeine is a 'biologically active substance', the existing conditions for making nutrition content claims about biologically active substances would apply to claims about the presence or absence of caffeine on FSSF. The proposed advisory statement 'contains caffeine' and the proposed declaration of caffeine in the NIP would not constitute nutrition content claims as these would be mandatory requirements and therefore not claims.

The health claims that may be made on labels or in advertisements for food and the conditions under which such claims may be made are set out in Standard 1.2.7 of the Code. In addition to those provisions, section 2.9.4—7 prohibits an express or implied representation that relates any property or proposed use of FSSF to enhanced athletic performance or beneficial physiological effects on the label on a package of FSSF, unless specific permission is given.

Division 3 of Standard 2.9.4 permits products that meet one of three types of compositional specifications (high carbohydrate supplement, protein energy supplement, or energy supplement) to be labelled with claims about their use in association with exercise. For

example, all three products may be labelled with claims to the effect that the product is useful before, during or after sustained strenuous exercise; an energy supplement may include claims to the effect that it may assist in supplementing the diet with an energy source as may be required during training.

FSANZ did not propose any amendments to the current provisions in the Code for claims as they apply to FSSF via this proposal.

2.2.10.1 Submitter comments

Submitters were supportive of the approach proposed in the 1st CFS for health claims, with some making specific suggestions in relation to the regulation of health claims about FSSF (summarised in Table F of Appendix 1).

2.2.10.2 FSANZ response

FSANZ has not identified any reason to amend the current provisions for claims about FSSF as a result of the proposed specific permission to add caffeine to FSSF. The regulation of claims for FSSF is not included in the scope of this proposal but is being reviewed by FSANZ under P1010 and the suggestions made by submitters in response to the P1056 1st CFS will be considered and discussed under that proposal.

Under the current Code provisions, FSANZ considers that the claims permitted about certain products in Division 3 as described above could be made about those products when they contain caffeine. An express or implied representation that relates caffeine to enhanced athletic performance or beneficial physiological effects on sports foods, however, could not be made (section 2.9.4—7 of the Code).

2.2.11 Risk management conclusion

Following consideration of submitter comments, FSANZ is proposing the following risk management measures for the regulation of caffeine in the general food supply.

- An express prohibition on caffeine being sold as a food for retail sale unless expressly permitted by the Code.
- An express prohibition on a food for retail sale containing caffeine as an ingredient or component unless expressly permitted by the Code.
- An express permission for a FSSF to contain a maximum of 200 mg of caffeine in a one-day quantity, in conjunction with labelling requirements.
- Additional restrictions for certain types of FSSF including retaining the current 5% maximum limit for powders and introducing individual packaging requirements for small volume, solid and semi-solid FSSF.
- An express prohibition of the presence of caffeine at a concentration of 1% or more in a FSSF that is a liquid (in conjunction with a maximum 200 mg one-day quantity of caffeine).
- A required advisory statement using wording to the effect of ‘contains caffeine’ on the label of all caffeine-containing FSSF.
- A required warning statement for caffeine-containing FSSF stating the following: *Not suitable for children under 15 years of age or pregnant or breastfeeding women: Should only be used under medical or dietetic supervision.*
- A requirement to declare the average quantity of caffeine present (from all sources) in any FSSF containing caffeine. Caffeine content would need to be declared in mg, on a per serving and per unit quantity (100 g or 100 mL) basis, in the NIP, following the entry for sodium.

The Code's existing novel food provisions would continue to apply to caffeine-containing plants or plant extracts that are also novel foods. These will require an application to FSANZ for permission to sell as a food or add an ingredient in food for retail sale.

No amendments are proposed to the Code's current claims provisions as they apply to FSSF.

2.3 Risk communication

2.3.1 Consultation and Communication

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this proposal. All submissions received are considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

The release of this 2nd CFS is supported by a media release, updated website information and public notification via Food Standards News and social media channels.

FSANZ has prepared a communication strategy for this proposal, which includes a range of communication strategies with key stakeholders and information for the broader community.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are not any relevant international standards regarding caffeine, however amending the Code to provide specific permission for the addition of caffeine to FSSF and prohibit its addition to other foods unless specifically permitted may have an effect on international trade. Therefore, a notification to the WTO under Australia and New Zealand's obligations under the WTO Technical Barriers to Trade and Application and a Sanitary and Phytosanitary Measures Agreement have been made to enable other WTO members to comment on the proposed amendments.

2.4 FSANZ Act assessment requirements

When assessing this proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

2.4.1 Section 59

2.4.1.1 Consideration of costs and benefits

FSANZ has considered the cost and benefits of this proposal, which is presented in detail at SD5.

A consultation regulation impact statement (CRIS) has not been prepared, because the function of the CRIS has been achieved by this document and the statutory consultation that has been undertaken in the 1st CFS and this 2nd CFS. The Office of Impact Analysis (OIA) has agreed with this decision and provided an exemption[15]. FSANZ will prepare a decision regulation impact statement that will accompany the Approval Report.

In summary, the analysis found that the most significant impacts of this proposal are:

[15] The OIA reference number for this proposal is OIA24-07750

- Quantified costs[16]
  - reformulating caffeinated products presented as sports foods – A$1.3m to $2.5m
  - relabelling caffeinated products presented as sports foods – A$1.8m to $3.7m
- Unquantified benefits
  - greater regulatory certainty for industry and governments, with flow on benefits to consumers
  - improved health and wellbeing outcomes for consumers.

The total cost of the proposal is A$3.1m to $6.2m. Some of these costs may be passed on to consumers.

FSANZ expects that the proposal will lead to a net benefit to society. A break-even analysis shows that daily users of caffeinated sports foods will need to receive benefit of only $1 to $2 per year for the benefits of the proposal to exceed the costs.

Stakeholders are invited to comment on this analysis.

2.4.1.2 Other measures

FSANZ has not identified other measures that would be more cost-effective than varying the Code as proposed, to address the identified risks.

2.4.1.3 Any relevant New Zealand standards

New Zealand food law includes the *New Zealand Food (Supplemented Food) Standard 2016*. This Standard is discussed in section 1.4.3. Refer also to section 2.5.1 of the P1054 Amendment report (FSANZ 2020).

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ has assessed the relevant scientific evidence on the risks to public health and safety arising from foods containing caffeine, as well as risk management measures currently in place such as maximum permitted levels of caffeine and advisory statements for certain foods. The assessment indicates that some risks exist to the health and safety of consumers (sections 2.2 and 2.3.1.2). As stated above, caffeine is a substance that has maximum daily intake recommendations, that vary depending on age and population group (SD1).

These assessment findings have informed the proposed regulatory measures set out in the draft variation prepared following the consideration of submissions. These measures aim to protect public health and safety by limiting the potential for excessive caffeine intake through the consumption of products containing high levels of added caffeine and reduce the likelihood of the addition of caffeine becoming more widespread in the general food supply (refer to section 2.2 of this report).

2.4.2.2 The provision of adequate information relating to food to enable consumers to

[16] The quantified costs consider the proposed two-year transition period

make informed choices

The current advisory statements required for a limited range of products that contain caffeine (see section 1.4.1.8 above) assist consumers to make informed choices about foods containing caffeine. FSANZ has also considered advisory statements and labelling of caffeine content on FSSF containing caffeine (see section 2.2.6 above).

2.4.2.3 The prevention of misleading or deceptive conduct

FSANZ has not identified any relevant issues.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ's risk analysis considered the best available scientific information currently available. FSANZ had regard to prior assessments regarding caffeine permissions in the Code (Attachment 1, 1st CFS) (FSANZ 2022), as well as P1054 (FSANZ 2020). Additional information was sought from stakeholders through the 1st CFS.

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

There are no relevant Codex food standards relating to addition of caffeine to food. See above in section 1.4.4 for provisions in other countries.

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

As detailed in the Costs and benefits analysis (SD5), amending the Code as proposed may provide the food industry:

- regulatory certainty, potentially enabling greater investment and returns
- improved reputation with consumers, potentially increasing sales
- a fairer market, with an increased likelihood non-compliant products will be removed from the market.

For FSSF, regulatory certainty is likely to lower regulatory risk and may reduce costs and increase investment.

Domestically produced products have a reputation as being 'clean' and safe in international markets, which enables domestic manufacturers to capture more of the export product market (IBISWorld, 2023). It is expected that this proposal will further improve this reputation.

See SD5 for details and Table B of Appendix 1 for submitter comments about international harmonisation, trade, and cost to industry of the proposed amendments to the Code.

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

FSANZ has not identified any issues to date.

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

FSANZ must have regard to any written policy guidelines formulated by the Australia and New Zealand Ministerial Forum on Food Regulation[17] (now known as the Food Ministers' Meeting). There are three policy guidelines relevant to this proposal:

- Ministerial Policy Guideline – Regulatory Management of Caffeine in the Food Supply
- Policy guideline – Addition to Food of Substances other than Vitamins and Minerals

[17] Available at Food Regulation – Ministerial Policy Guidelines (accessed 24 July 2024)

- Policy Guideline on the intent of Part 2.9 of the Food Standards Code – Special purpose foods.

Each of these Guidelines is summarised in the 1st CFS.

FSANZ had regard to each Guideline in its assessment and when preparing the draft variation. FSANZ considers that that assessment and the draft variation address each.

3 Draft variation

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

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

3.1 Transitional arrangements

The draft variation proposed by FSANZ provides transitional arrangements. In developing these transitional arrangements, FSANZ considered the risk to public health and safety, the regulatory changes proposed, the range of products on the market required to reformulate and adopt the proposed labelling requirements, the costs and practicalities of transition for industry, stakeholder views, precedents for transitional arrangements and other relevant FSANZ proposals and applications.

FSANZ proposes a transition period of two years that begins on the date of gazettal of the draft variation (i.e. introduction of all proposed amendments). During the transition period, a food could comply with either the Code as in force without the variations made by the draft variation, or with the Code as amended by the draft variation.

3.1.1 Rationale for the proposed approach

The two-year transition period balances minimising costs for businesses, particularly for smaller businesses where costs may be disproportionally higher, with not unduly delaying the amendments. A transition period greater than two years may unnecessarily prolong the implementation of the proposed amendments with a resulting cost to public health and safety. FSANZ considers the caffeine concentration limits put in place through P1054 manage the risk to the Australia and New Zealand population from highly concentrated forms of caffeine during this transition period. The approach balances minimising costs for businesses with minimising the risk to vulnerable sub-populations.

At the 1st CFS, industry stakeholders suggested that labelling changes and reformulation could take between 6 and 36 months. FSANZ considers a transition period of two years is appropriate given required labelling changes that will directly impact the FSSF category and FSSF retailers and distributors. This change is commensurate with the transition periods recently afforded to other applications and proposals requiring possible compositional and label changes (for example P1030 – Composition and labelling of electrolyte drinks) and recognises the relatively long shelf-life of FSSF.

3.2 Education

Consumer education is important to support consumer awareness of the risks associated with caffeine consumption.

FSANZ has a number of channels available to reach target audiences and disseminate messages, including the FSANZ subscription service, the FSANZ website, social media and attendance at meetings, events and conferences. Consumer education materials on the risks of pure and highly concentrated caffeine products are already on the FSANZ website and these would be updated to ensure consistency with the new requirements for caffeine in food, if approved.

Based on feedback from submissions to the 2nd CFS and ongoing discussions with jurisdictions, FSANZ will consider the best way to approach consumer education on caffeine in the food supply. FSANZ anticipates working cooperatively with these organisations to ensure consistency of information and to maximise the effectiveness of available resources.

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Appendices

1. FSANZ response to issues raised in submissions to the 1st CFS
2. Ergogenic effects of caffeine: findings of peak bodies

Attachments

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

Appendix 1 FSANZ response to issues raised in submissions to the 1st CFS

Note: Issues in column 1 of all tables below have been grouped according to subject. Column 3 indicates the submitters or submitter groups who raised issues about that subject. However, not all of the issues within each subject grouping are necessarily the representative view of the submitters listed for that group.

Table 1: Submitters to the 1st CFS

Organisation	Abbreviation
Aldi Australia	Aldi
ATP Science Pty Ltd	ATP
Australian Association of Convenience Stores	AACS
Australian Beverages Council	ABCL
Australian Food and Grocery Council	AFGC
Australian Institute of Sport	AIS
Complementary Medicines Australia	CMA
Department of Agriculture, Fisheries and Forestry	DAFF
Dietitians Australia	DA
Frucor Suntory	Frucor
New South Wales Poisons Information Centre	NSWPIC
New South Wales Food Authority	NSWFA

New Zealand Beverage Council	NZBC
New Zealand Food and Grocery Council	NZFGC
New Zealand Food Safety	NZFS
Queensland Health	QLDH
South Australia Health	SAH
Sports Dietitians Australia	SDA
Tasmanian Department of Health	TAS DoH
The Hut Group	The Hut Group
Victorian Departments of Health and Energy, Environment and Climate Action	VIC DoH and DEECA
Western Australia Department of Health	WA DoH

Table A: Proposed regulatory options – submitter comments and FSANZ responses

Comment	Raised By	FSANZ Response
In the 1st CFS, FSANZ proposed the following under option 3: *• to explicitly permit in FSSF, total caffeine up to 200 mg in a one-day quantity* *• an express prohibition on the addition of caffeine to other foods for retail sale, other than those that have a specific permission i.e. cola-type drinks and FCBs* *• removal of the P1054 variation.* *The following submitters provided comments on the topic.*		
Supported, in principle, FSANZ's Option 3 approach. Some additional specific comments included: • It provides regulatory clarity. • It supports innovation in the non-alcoholic beverages industry. • Providing it ensures safety for vulnerable sub-populations. • Support subject to reviewing the drafting. • Provides the right balance to support consumer health, innovation, and trade. • Explicit prohibitions are necessary for regulatory clarity and careful management of caffeine is necessary given market trends of increased availability and promotion of caffeine-containing beverages. • Aligns with the Ministerial *Policy Guideline – Regulatory Management of Caffeine in the Food Supply (2014)* regarding vulnerable population groups, exposure from all sources and be informed by emerging evidence and regulation in overseas jurisdictions. • Providing all references to caffeine relate to all sources in the drafting (e.g. guarana, green tea extract). • Overall approach has merit in the reduction of overall risk of caffeine exposure but does not address the risk of caffeine toxicity from concentrated products. • Support in principle all except a pre-market assessment process which could allow caffeine in other foods (risk	AFGC, DAFF, ABCL, Frucor, NZBC, QLDH, SAH, AACS, NSWPIC, NZFS, VIC DoH and DEECA, SDA, TASDoH	FSANZ notes these comments. FSANZ has prepared a draft variation to implement Option 3 and to prohibit the retail sale of a food that is caffeine (see section 2.3 and Attachment A – Draft variation). The limits on the amount of caffeine that can be present in a food (FCBs and as proposed for FSSF) are intended to apply to all caffeine present in that food including from a plant source (refer to section 2.2.5 of this report and Item 5, Attachment A). Refer to section 2.2.1.2 of this report which outlines how the proposed amendments are intended to reduce the risk to vulnerable sub-populations including children and pregnant women. This section also explains how the proposed amendments are also intended to ensure safe and continued access to caffeinated products for consumers. Refer to section 2.2.4 on FSANZ's proposed approach to address the risk of caffeine toxicity from concentrated products. A pre-market assessment to amend the Code is available through an application to FSANZ at any time. Any application to FSANZ must demonstrate safety for the proposed changes in accordance with the requirements in the FSANZ Application Handbook.

Comment	Raised By	FSANZ Response
exists of inadvertent high caffeine intake for non-informed consumers).		
The current permission in 1.1.1—10(5)(g) can be interpreted in a way that allows caffeine to be added to any food or beverage for retail sale so long as it is below the thresholds set out (>5% for solid or semi-solid foods and >1% for liquid foods), a general prohibition will provide clarity.	AFGC	Current paragraph 1.1.1—10(5)(g) is expressly stated as a prohibition and does not and cannot create or constitute a permission to add caffeine to all foods up to a limit of 1% or 5%. See each of the published P1054 reports on this point.
These submitters supported some aspects of FSANZ's approach or an amended version. Some specific comments included: • Support permission in FSSF but should retain P1054 amendment so that high dose, low volume caffeinated goods cannot be sold, and highly caffeinated extracts are regulated. • Labelling and permitted amount in FSSF will help inform users of the caffeine content but will not reduce access to large amounts of caffeine in concentrated products. • Consider the implications of transition periods to avoid any gap in regulatory coverage. • Supported an amended Option Two from the 1st CFS whereby inclusion of exemptions for selected foods to which caffeine could be added in the future, prohibition could present as a major impediment to flavourings and ingredients. • Support some but not all of FSANZ's proposed approach and in addition, there are inconsistencies with the approach to caffeine labelling across the varying food categories	NSWFA, NSWPIC, NZFGC, THG	See response above for FSANZ's proposed amendments. Regarding the P1054 amendments and access to concentrated caffeine products, FSANZ recognises the need to reduce the risk of inadvertent consumption of excess caffeine via caffeine-containing low volume FSSF and is proposing specific packaging requirements for low volume solid and semi solid FSSF (such as chewables and strips) and compositional requirements for liquid and powdered FSSF. See section 2.2.4. Together with the proposed maximum level of a 200 mg one-day quantity of caffeine and labelling requirements, FSANZ considers this appropriate for managing the risks associated with FSSF containing caffeine. The proposed transition period for the amendments is outlined in section 3.1. During the transition period, a food can comply with either the Code as in force as if the variation had not taken effect, (including the variation made via P1054) or with the Code as amended by the variation. Regarding the suggestion for an amended Option Two with exemptions for certain products, the Code already provides two avenues whereby caffeine has an express permission for addition to foods. Based on the risk assessment (section 2.2) and informed by consultation in the 1st CFS and the proposed permission to allow caffeine in FSSF, FSANZ considers exemptions unnecessary. The proposed amendments will not prevent food businesses from applying to FSANZ to amend the Code if they wish to add caffeine to a food in the future. The different labelling requirements across different products (cola beverages, FCBs, and as proposed for FSSF for example) are based

Comment	Raised By	FSANZ Response
		on the nature of the product itself, caffeine content and associated level of risk. Refer to section 2.2.6 for further detail.
Should be no premarket assessment requirement to put caffeine in general food, manufacturers unlikely to put high levels of caffeine in foods. Proposed a maximum level of caffeine for general foods that is lower than those proposed for FSSF and permitted for FCBs and cola type drinks. Suggest premarket assessment only if want to add over 100 mg (daily) to a product.	Aldi	FSANZ considers the chronic and acute risks associated with consumption of caffeine, as well as the potential addition of caffeine to foods without specific regulation in place, are sufficient to justify the proposed approach for pre-market assessment. See section 2.2.1.2 for further rationale.
Prefers Option One (Status Quo) from the 1st CFS as there is no overwhelming risk within the current market for educated adult users. Do not believe pre-market assessment is required to add caffeine to food. FSANZ's options will drive consumers to overseas sports food products, create their own products in non-regulated ways or to seek illegal drugs to gain the highs and performance gains that they were previously able to get with reasonable and safe doses of caffeine.	ATP	See above response regarding pre-market assessment. FSANZ considers that the proposed one-day quantity of caffeine in FSSF in conjunction with labelling requirements, would provide consumers with a safe and reasonable dose of caffeine for sports performance. FSANZ disagrees that there is no risk for certain sub-populations of adult caffeine consumers. See sections 2.2 and 2.2.1.2 for further discussion on these risks. Given that products complying with the Code will be permitted to contain caffeine, it is unlikely this proposal will be the reason consumers decide to buy illegal substances.
Supported the general prohibition of caffeine in all foods and that a pre-market assessment is required to add caffeine however called for a review of the caffeine levels added to cola beverages, FCBs and FSSF.	WADoH	The levels of caffeine in formulated caffeinated beverages (FCBs) and cola-type beverages have already been assessed by FSANZ as safe and accepted by Food Ministers. FSANZ also notes that the most recent safety assessment conducted under P1056 did not identify any evidence that the permitted caffeine content of FCBs or cola beverages should be changed.
This submitter noted the following in SD1: • Section 2.6.9.3, suggest also specifying the effect from Krebs et al., 2012. • The conclusions in section 2.8 leave it ambiguous what the point of departure dose should be for risk assessment (i.e. 1.4 vs. 3.0 vs 5.7 mg/kg/day). Suggest this is more directly stated for clarity.	NZFS	FSANZ notes the following: • The effect is increased blood glucose, as stated in section 2.6.9.3. • 5.7 mg/kg bw/day is the appropriate point of departure (POD) for adolescents. FSANZ considers 3.0 mg/kg bw/day the appropriate POD for children, since some sleep disturbance (which may occur at ≥ 1.4 mg/kg bw/day) if caffeine is consumed late in the day is a predictable effect in all age groups

Comment	Raised By	FSANZ Response
		and is not considered an adverse effect. Increased anxiety is considered to be adverse.
Suggest the finding in SD3 that 'There was no evidence of overconsumption of caffeine in children based on Australian/New Zealand studies' is reviewed. One study suggested that at least some 8-12 year-old South Australians were consuming caffeine over the recommended daily maximum (>120 mg/day), although the exact number was not mentioned in the study. In addition, this finding is not based on New Zealand studies as there were no studies available.	NZFS	The finding in SD3 has been modified to acknowledge the absence of New Zealand-based studies. FSANZ notes the available evidence does not suggest any significant overconsumption of caffeine by children.

In the first CFS, section 1.4 discussed the addition of plant extracts and concentrated forms of caffeine stating that:

- ***P1056 is considering the addition of caffeine to foods, where permitted, regardless of the source (i.e. synthetically produced or from a plant source such as guarana extract).***
- ***When plant sources of caffeine are prepared as food ingredients, they can be intentionally concentrated and standardised. Some plant sources of caffeine, whether the whole plant or an extract from a plant source, may meet the definition of a novel food in the Code and require a pre-market assessment before they can be added to food irrespective of the purpose of addition to food.***
- ***Whether or not a particular plant source of caffeine meets the definition of a novel food is not within the scope of this proposal.***

The following submitters provided commentary on this topic.

Comment	Raised By	FSANZ Response
Regarding plant extracts containing caffeine, the following was suggested by some submitters: • Set an upper limit for foods and extracts containing caffeine. • The removal of the P1054 variation would not address safety risks from extracts (for examples, extracts advertised on the internet containing 22 % caffeine) • Caffeine added as a pure concentrated product should still be regulated. • Any food extract that is high in caffeine and therefore close to the upper limits could be defined as 'caffeine' in the Code. • FSANZ must provide legal clarity in regard to the retail sale of high caffeine extracts and proprietary blends because	QLDH, NZFS, NSWFA, NSWPIC	See above for the proposed approach to prohibit the retail sale of caffeine unless specifically permitted. The caffeine component both added as a pure substance and from a plant extract to FBCs and FSSF is intended to be included in the maximum permitted levels for caffeine content. This means the amount of any synthetically produced caffeine and caffeine from a plant source must be summed and cannot exceed maximum limits (refer to 2.6.4—3(a) of the Code, section 2.2.5.2 of this report and Attachment A, Item 5). FSANZ is not proposing to define and regulate caffeine-rich extracts as 'caffeine' or to apply the 200 mg one day quantity labelling requirement to all foods. It is likely that a number of caffeine-rich extracts would be unapproved novel foods which, consistent with the current Code provisions, could not be used as an ingredient in a food

Comment	Raised By	FSANZ Response
these could otherwise be considered 'foods' and permitted by the Code. • Consider defining caffeine rich extracts above a certain concentration as 'caffeine' for the purposes of the proposed express prohibition (noting that requirements relating to the type of method for extracting caffeine (e.g. limiting to water extraction only) are difficult to enforce. • Clarity in the drafting for when coffee, tea or chocolate are no longer compliant noting that coffee extract is used as a flavouring and cold brew products contain coffee concentrate. • A limit applied to coffee, tea and other foods with naturally occurring caffeine (a 25 ml bottle of coffee concentrate product labelled as containing 12 shots was ingested by each of two individuals both of whom developed symptoms consistent with caffeine toxicity. If each 'shot' contains equivalent to the FSANZ suggested 80-95 mg caffeine, this would equate to 960-1140 mg per bottle or 3.8-4.5% w/v caffeine). • Retain the maximum limits for caffeine in paragraph 1.1.1—10(5)(g) but possibly still too high. • Suggest applying a 200 mg limit to all foods already permitted to contain caffeine. The largest volume FCB that can be readily purchased is a 500 mL can. If increased to 750 ml, it could theoretically contain 240 mg caffeine under the Code. This would prevent intentional concentration of naturally occurring sources of caffeine (e.g. guarana) being used as a food ingredient in combination with synthesized caffeine.		for retail sale or be sold as a food for retail sale. See section 2.2.5.2 No specific provisions are proposed for the sale of tea, coffee or chocolate, consistent with the current approach in the Code and overseas regulation. Noting that coffee is a major contributor to over consumption of caffeine in some population groups, FSANZ considers that education regarding caffeine intake is important. With respect to foods such as concentrated coffee products for retail sale, these must be labelled with directions for use if required for health or safety reasons, under current requirements in Standard 1.2.6 of the Code. FSANZ has not identified a risk that would justify amending the provisions for FCBs. This is based on the outcome of FSANZ's safety assessment (see section 2.2 and SD1 of this report) and the existing risk management measures for FCBs containing the maximum caffeine concentration; responsibility of the manufacturer for labelling with the 'normal' serving size for the purposes of the nutrition information panel; combined with some reliance on typical consumption behaviours by consumers, as there is for any caffeine containing food. There are additional labelling requirements advising that no more than a specified one-day quantity should be consumed if the FCB contains certain substances (see section 1.4.1.6 in this report). FSANZ considers issues such as overconsumption are best addressed through broader public health and safety policy on the safe consumption of caffeine in food. FSANZ notes that both the Australian Beverage Council[1] and NZ Beverage Council[2] provide information about FCBs for consumers and have industry commitments relating to the sale and promotion of FCBs, including to not promote excessive consumption. Given the above and the new proposed approach, FSANZ is not proposing to apply the 1% and 5% maximum limits for caffeine in paragraph 1.1.1—10(5)(g) to any foods except as proposed for FSSF (see sections 2.2.2.2 and 2.2.4of this report). 1 Available at Energy Drinks - Australian Beverages

Comment	Raised By	FSANZ Response
		2 Available at Energy Drink — NZBC
Suggest amending section 28—2 (FCBs) with a maximum permissible quantity of 200 mg per unit sold and amendment to 2.6.4—3(b) so caffeine becomes a 'listed substance'. Suggest applying the maximum 200 mg one-day quantity to all foods containing caffeine, regardless of the source of caffeine, so that food regulated under subsection 1.1.1—10(7) would not be exempt from a 200 mg caffeine one-day quantity threshold, which would prevent the shifting of large caffeine doses per unit sold from FSSF to FCBs.	NSWFA	Refer to FSANZ's response above relating to the rationale for not amending the FCB provisions via P1056. Additionally, it is noted that FSANZ has not proposed a maximum permissible quantity of caffeine per unit sold for any food, except for powdered and liquid FSSF (see section 2.2.4 of this report). With regard to subsection 1.1.1—10(7) of the Code, the total amount of caffeine present, regardless of its source, is intended to be included in maximum permitted levels (see section 2.2.5.2 of this report).
At the 1st CFS, FSANZ also asked the following question in Section 3.3.2: ***For product developers considering the addition of plant or other extracts containing caffeine, do you consider these would meet the definition of a novel food and therefore require a pre-market safety assessment?***		
The following comments were provided by some submitters: • If the extract is one which is currently not an ingredient that can be shown to have a long and safe history of use, then it is potentially a novel food. • If this extract which does not have a long history of tradition and safe use also contains caffeine, then it too will need to be assessed for safety as a novel food, but this is independent of its caffeine content. • A serving of the novel extract would need to meet current regulations for caffeine content in foods (which will presumably remain the same – i.e. a manufacturer may use an ingredient to 'dose up' the caffeine content of food beyond that which is currently allowed). • Confusion as the term 'extracts' is not explained in the CFS and where mentioned, refers to guarana extracts (i.e. what about tea and coffee?). • Recommended an exclusion for beverages, based upon coffee, tea and their extracts, is put into place in line with	AFGC, NZFGC, Aldi, ATP	FSANZ notes these comments. The FSANZ application process enables anyone to submit an application to FSANZ to amend the Code to permit an ingredient that is not currently permitted in the Code. FSANZ would conduct a comprehensive assessment, including a safety and dietary exposure assessment specific to the Australian and New Zealand population. Please see the FSANZ website[18] for more detail. FSANZ has further clarified its approach to extracts and sources of caffeine such as tea and coffee in section 2.2.5 of this report. The US GRAS system is not comparable to the premarket assessment requirements for novel foods in Australia and New Zealand. Comment is noted.

[18] Changing the code | Food Standards Australia New Zealand

Comment	Raised By	FSANZ Response
the European legislation mentioned on p53 of the P1056 CFS. • Caffeine containing plant extracts are not a novel food with years of safety data and GRAS status. • As long as the total caffeine is listed on the product label, individual consumers can judge for themselves.		
At the 1st CFS, section 3.2.2 proposed the removal of the P1054 variation (i.e. prohibit the retail sale of a food in which caffeine is present in a concentration of 1% or more of the food if that food is a liquid and 5% or more of the food if that food is a solid or semi-solid food), as the proposed approach to expressly prohibit the addition of caffeine to foods, apart from the express permissions in cola-type drinks and FCBs, would still apply to the foods that were considered to pose a risk under P1054. *The following submitters provided comment.*		
Supported the removal of the P1054 variation noting the limits introduced by the Therapeutic Goods Administration should address risks from pure and highly concentrated caffeine products that are not foods.	SAH, DAFF	FSANZ notes this comment.
Disagreed with or suggested an alternative to the removal of the P1054 variation with some submitters noting the following: • Concentrated caffeine powder is still being used in Australia (see NSWPIC submission for details), removal of the P1054 requirement does not prevent concentrated caffeine products from being sold and poses risk of caffeine toxicity. • The 1 and 5% limits currently in place lower the risk to consumers but are still quite high and should be lowered or could be considered arbitrary. • Unlike FCBs and cola drinks, the proposed 200 mg one-day quantity does not limit total quantity. The removal of the P1054 variation could permit pure and highly concentrated caffeinated FSSFs (i.e., containing multiple one-day quantities within the one container). This is not consistent with the original intent of the P1054 review. Recent changes to the *Therapeutic Goods Act 1989* mean that such products would be regulated as therapeutic goods. Suggest an explicit caffeine limit for FSSFs in the	NSWPIC, QLDH, NSWFA, VIC DoH & DEECA	The proposed express prohibition in section 1.1.1—10 (see Attachment A) would mean the only foods for retail sale permitted to contain caffeine (unless present by natural occurrence) are FCBs, cola-beverages and FSSF (as proposed under this proposal). All have restrictions on the amount of caffeine that the product can contain. A food for retail sale that is pure caffeine would be prohibited. A FSSF in a powdered form would be prohibited from containing caffeine at a concentration of 5% or more. FSANZ considers that the proposed express prohibition combined with the existing concentration limits for caffeine in FCBs, cola-beverages and the proposed approach for FSSF remove the need for the 1% and 5% limits currently in place. FSANZ has however, considered retaining concentration and packaging limits for certain FSSF that could comply with the maximum one-day quantity but potentially lead to high intakes of caffeine. See section 2.2.4 of this report for discussion on how concentration limits would apply to certain FSSF that contain caffeine. Under the proposed requirements, a manufacturer could not recommend consuming an amount of a FSSF that would result in

Comment	Raised By	FSANZ Response
Code (see the Departments' P1054 submission for suggestions on compositional limits).		consumption of over 200 mg of caffeine in one-day on the label of that FSSF.
Disagreed with the proposed approach based on an online search showing products that would not be permitted under current requirements could legally be sold in Australia and New Zealand should the P1054 limits be withdrawn e.g. a guarana extract powder search returns multiple products claiming to contain at least 22% caffeine.	QLDH	For foods, the proposed approach to prohibit the addition of caffeine as an ingredient or component to foods for retail sale unless expressly permitted would mean that guarana extract sold for retail sale would not be permitted to contain added caffeine unless the food was a cola beverage, FCB or (as proposed in this proposal) FSSF and complied with the MPL.

Table B: International harmonisation, trade, and cost to industry – submitter comments and FSANZ responses

Comment	Raised By	FSANZ Response
At the 1st CFS, sections 1.5.6, 3.2.1.4, 3.2.2 and 3.5 FSANZ discussed and called for comment on the costs to industry and trade and international regulations on caffeine. *The following submitters provided comment.*		
There is an ongoing issue of imports of caffeinated foods that undergo limited compliance checking at the border. These are often non-compliant with the Code.	AFGC	The surveillance and enforcement of imported products in Australia is the responsibility of the Department of Agriculture, Fisheries and Forestry (DAFF).
Noted that the cost to industry will only be to those manufacturers that wish to add caffeine to their FSSF after the proposed changes are made.	ABCL, Frucor NZBC	FSANZ notes this comment.
Noted that the current risk classification of food as part of the Imported Food Control Order 2019 (the Order) for retail sale will likely need to be revoked following a review of the risk advice provided by FSANZ. Note that most imported food is referred to the Imported Food Inspection Scheme (IFIS) at the surveillance rate of 5% except when it is classified as a risk food in the Order.	DAFF	FSANZ notes this for future work.
Requested FSANZ consider the potential for the *Trans-Tasman Mutual Recognition Act 1997* (TTMRA) between Australia and New Zealand to be used as a loophole to import highly concentrated caffeine products even if they would not be	DA	The operation of the TTRMA is a matter for the Australian and New Zealand governments and out of scope of the proposal. FSANZ notes that highly concentrated caffeine products are not permitted for retail sale in New Zealand under the New Zealand

Comment	Raised By	FSANZ Response
allowed for import to Australia from a different country.		Supplemented Food Standard. See section 1.4.3 and 2.5.1.3 for further information.
FSANZ should consider regulation that aligns with international standards and guidelines available.	Aldi	In assessing this proposal and in preparing the draft variation, FSANZ had regard to international standards and the need to promote consistency between domestic and international standards. See Appendix 2 of this report and Attachment two of the 1st CFS (FSANZ 2022).
Cited extensive costs and SKUs that would be impacted in order to withdraw and dispose of existing products and to reformulate, re-label and market new product (estimated costs were provided). This would be a strain on a medium-sized Australian business, including job losses. The proposed regulation gives more opportunity to overseas imported products, and black-market products. Noted they are developing a new caffeine-containing pre-workout product and had the potential to introduce nootropic style powdered beverages for the computer gaming enthusiast in the future.	ATP	The cost of relabelling and reformulating impacted products is considered in the cost benefit analysis (see SD5). The transition period of two years is intended to provide sufficient time for existing products to be sold, and to minimise the cost of reformulation and relabelling. FSANZ notes that these cost impacts are in the short-term. These costs should be weighed against potential benefits to businesses that occur over the longer term, including regulatory certainty created by the regulation. They should also be weighed against the public health and safety benefits of the proposal. This is discussed in the cost benefit analysis (SD5). It is not clear that the proposal will result in greater demand for imported products relative to domestic products, noting that 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. FSANZ is not aware of any evidence to suggest a significant number of consumers will to turn to the black market as a result of this proposal. Given that products complying with the Code may still contain caffeine, it is unlikely this proposal will be the reason consumers decide to buy black market products.
At the 1st CFS, FSANZ asked the following question in section 3.3.2: ***To what extent do you agree that there are relatively few general foods (i.e. not FSSF) that contain added caffeine (i.e. foods that will be impacted by the proposal) and are currently sold in Australia and New Zealand?***		
The following comments were provided in response:	DA, Aldi	Refer to above response in Table A outlining how FSANZ is proposing to amend the Code. FSANZ proposes to regulate the

Comment	Raised By	FSANZ Response
• Green tea extract is being added to products such as formulated meal replacements and ketone shots without caffeine being on the label, the amount of caffeine can vary greatly. • Market trends show an increase in caffeinated products and demand for weight management, exercise related products.		caffeine content of food, regardless of its source. Refer also to the ACNF determination that green tea extract is a novel food (see ACNF Record of Views[19]) and no permission exists in the Code for addition of green tea extract as a novel food ingredient to food for sale (see section 2.2.5 for further discussion on extracts and novel foods).
This submitter noted that data gathered by NZFS using the GS1 On Pack database suggests there are relatively few general foods that contain added caffeine currently sold in New Zealand. Most are cola-type drinks and FCBs. Other products typically contain small amounts of naturally occurring caffeine.	NZFS	FSANZ notes this comment. See section 2.2.1.2 for further discussion.

Table C: FSANZ's proposal for an express prohibition on addition of caffeine - submitter comments and FSANZ responses

Comment	Raised By	FSANZ Response
At the 1st CFS, FSANZ proposed an express prohibition on the addition of caffeine to other foods for retail sale, other than those that have a specific permission i.e. cola-type drinks and FCBs. • ***FSANZ proposed that the existing permissions in FCBs, cola-type beverages are out of scope*** • ***This would not affect the ability to sell foods that contain caffeine by natural occurrence, for example coffee, tea and chocolate unless the novel foods provisions apply as mentioned in section 1.5.2.5*** • ***Businesses could apply (using FSANZ's existing processes) for explicit permissions for specific foods for retail sale to contain caffeine within the Code.*** • ***The prohibition would also not include FSSF*** *The following submitters provided comment.*		
These submitters agreed with FSANZ's intent to maintain existing caffeine permissions in cola type drinks or energy drinks (FCBS).	AACS, ACBL, Frucor, NZBC, AFGC, NZFGC, NZFS	FSANZ notes these comments.
Provided support for the express prohibition with the following comments (not all of the topics below are necessarily the	AFGC, NSWPIC, DAFF, QLDH,	FSANZ notes these comments.

[19] Novel food - Record of views formed in response to inquiries | Food Standards Australia New Zealand

Comment	Raised By	FSANZ Response
representative view of all the submitters listed): • Provides regulatory clarity and certainty for enforcement. • Hopes it will minimise new sources of caffeine and risk of stacking and toxicity. • Will simplify labelling inspections and reduce assessments with % calculations at the border. • A prohibition without express permission must be explicitly stated in the Code. • Will ensure the consumer market is not overwhelmed with caffeine containing products. • Difficult to find a justifiable purpose for caffeine in other foods other than cola drinks FCBs and FSSFs, a pre-market assessment seems unnecessary but acknowledges that it supports innovation. • Support case-by-case pre-market assessment in all foods. • Strong support for the continued permission for the presence of caffeine by natural occurrence. ***Specific issues / concerns*** • Concern it may lead to a loophole which permits the sale of high caffeine dose, low weight substances as foods (e.g. caffeinated chewing gum, energy strips and gels). Products are more appropriately regulated as therapeutics as the principal purpose of these products is the rapid delivery of a high dose of caffeine to an athlete (with no nutritional purpose i.e. no provision of electrolytes, nutritive substances or hydration). • Must ensure that the current general prohibition on the use of a novel food will apply to novel plant sources of caffeine	NSWFA, NZFS, VIC DoH and DEECA, DA, AIS	After consideration of submissions and for the reasons summarised on this CFS, FSANZ has prepared a draft variation to prohibit food for retail sale containing caffeine as an ingredient or component unless expressly permitted by the Code. See proposed amendments to subsections 1.1.1—10(5) and (6) in the draft variation (items 1 and 2 of the draft variation). Subsection 1.1.1—10(7) is retained, which would have the effect that a food for sale may have caffeine as an ingredient or component of the food if the caffeine is in that food, or in an ingredient of that food, by natural occurrence. Regarding low volume, concentrated FSSF, the proposed regulations will require individual wrapping of solid and semi-solid FSSF when sold in packaging that includes individual portions (such as chewables and dissolvable strips), where the entire contents contains more than 200 mg caffeine. Section 2.2.4 of this report outlines this risk management approach. Regarding stacking, see further discussion below under FSSF, Table D. There are no proposed changes to the novel food provisions in the Code under P1056. If a manufacturer wishes to sell a novel food or a food containing a novel food ingredient, they must apply to FSANZ for the Code to be amended. In the first instance, they can obtain advice from the relevant food enforcement agency and/or obtain their own legal advice about whether a food is a novel food. They can also approach the Advisory Committee on Novel Foods (ACNF) to make a recommendation about whether a food is novel. See section 2.2.5 for further discussion. The Code currently does not prohibit the addition of caffeine unless expressly permitted. FSANZ does not agree that the intention of the Code has always been to prohibit the addition of caffeine in the food supply unless expressly permitted. See the published P1054 reports on this point.

Comment	Raised By	FSANZ Response
• Consider the intention of the Code has always been to prohibit the addition of caffeine to foods unless expressly permitted.		
Called for FSANZ to provide clarity on the process whereby a business could apply for a permission to add caffeine to a food that does not already have explicit permission. This is because it is unclear as to whether FSANZ will require a full application vs only a pre-market assessment and taking into consideration the associated time and costs for such an assessment.	ABCL, Frucor AFGC, NZBC	All applications and proposals for amendments to the Code must be assessed in accordance with the FSANZ Act.
Did not support the express prohibition with the following comments: • Proposed option potentially limits product development and consumer choice. • Caffeine is considered safe in most adults up to 400 mg per day, then including a statement of caffeine level on the label should be sufficient. Individuals can make their own informed decisions.	NZFGC	FSANZ's assessment identified that the consumption of caffeine, either from chronic (habitual) intake or through an acute (single) dose can have health effects. See section 2 of the 1st CFS and the safety assessment (SD 1), the dietary intake assessment (SD 2), the social science assessment (SD 3) and the assessment of caffeine and sports performance (SD 4). FSANZ notes evidence, including submissions received in response to the 1st CFS on an increasing trend in caffeine consumption. There are several avenues within the Code whereby manufacturers can add caffeine to products (see section 2.2.1.2). After consideration of all submissions received, FSANZ is not aware of any evidence that would warrant a change in approach in terms of the proposed prohibit unless permitted approach. As mentioned above, if manufacturers wish to amend the Code, they may submit an application to FSANZ.

Formulated Supplementary Sports Foods

Table D: One-day quantity – submitter comments and FSANZ responses

Comment	Raised By	FSANZ Response
In the 1st CFS, FSANZ proposed to **explicitly permit in FSSF, total caffeine up to 200 mg in a one-day quantity.** *The following submitters provided comment.*		
Agreed in principle with FSANZ's proposal to explicitly permit total caffeine up to a 200 mg one-day quantity in FSSF, noting the following (not all of the topics below are necessarily the representative view of all the submitters listed): • consistency with ergogenic benefit and safety evidence and overseas permissions • provision of greater legal clarity • combined with consumer education, will most likely reduce the risk of overconsumption of caffeine • consumers are still required to be aware of and adhere to recommended quantities.	AACS, ABCL, Frucor, NZBC, DAFF, NZFS, SDA, Qld, AFGC, NSWPIC, VIC DoH and DEECA, AIS	FSANZ notes these comments.
Supported an explicit permission for a 200 mg caffeine one-day quantity in FSSF but considered sports science about caffeine to be poor. Concerned that basing decisions for caffeine limits for athletes on poor science does not reflect well on the integrity of the system. The FSANZ report found a low level of certainty from the evidence that caffeine is beneficial for athletes in relation to time trials.	NZFGC	The maximum 200 mg one-day quantity of caffeine in FSSF was based on the safety assessment, which concluded that a single acute dose of up to 210 mg in adults and a daily amount of up to 400 mg is not associated with adverse effects in the general adult or adolescent populations (SD1). Consumption over these levels may pose health and safety risks. This amount also considers general consumption of caffeine by the Australian and New Zealand populations from sources other than FSSF. The ergogenic effect of caffeine was considered separately. FSANZ assessed the evidence on the effect of caffeine on sports performance using data from 39 human time trial performance studies in sports including cycling, running, rowing and swimming. The overall conclusion was that caffeine had a small statistically significant beneficial effect on sports performance compared to placebo. The level of certainty in the evidence was downgraded because time trial performance in athletes does not represent the general Australian and New Zealand populations, and due to risk of bias.

Comment	Raised By	FSANZ Response
		Further rationale for FSANZ's decision regarding the 200 mg limit can be found in section 3.2.1 of the 1st CFS (FSANZ 2022) and section 2.2.3.2 of this report.
Supported FSANZ's proposal to explicitly permit the addition of a 200 mg one-day quantity of caffeine to FSSF. However, is concerned that applying the restriction to FSSF only provides means for larger caffeine doses to be legally introduced into other foods, such as FCBs.	NSWFA	Refer to above response: FSANZ has not identified a risk that would justify amending the provisions for FCBs. This is based on the outcome of FSANZ's safety assessment (see section 2.2 and SD1 of this report) and the existing risk management measures for FCBs of a maximum caffeine concentration; responsibility of the manufacturer for labelling with the 'normal' serving size for the purposes of the nutrition information panel; combined with some reliance on typical consumption behaviours by consumers, as there is for any caffeine containing food. There are also additional labelling requirements advising that no more than a specified one-day quantity should be consumed if the FCB contains certain substances (see section 1.4.1.6 in this report).
Supportive of the approach however believe the risk to adolescents requires further consideration to ensure alignment with the *Ministerial Policy Guideline on the Regulatory Management of Caffeine in the Food* Supply. Suggested the recommended maximum level of caffeine for children and adolescents (10 to <18 years) should be reconsidered to align with international consensus (see submission for details). These sources concluded 2.5-3 mg/kg bw/day is appropriate for children and adolescents due to limited data on long term effects. Are concerned that under the proposed approach some adolescents may not be adequately protected from acute caffeine-related safety risks. Noted that a single dose of caffeine up to 210 mg (approx. 3 mg/kg bw) is not generally associated with any adverse effects. Gave examples of the maximum safe levels for adolescents with lower body weight than adults (165-192 mg). Compositional limits and labelling requirements as well as non-regulatory measures should be reconsidered given these risks. Know that young males are also higher consumers of sports	VIC DoH and DEECA TAS DoH	In assessing this proposal, FSANZ has had regard to several ministerial policy guidelines, including the *Ministerial Policy Guideline on the Regulatory Management of Caffeine in the Food Supply* (see section 2.4.3 of this CFS). Population groups considered in the assessment include the general population, pregnant and lactating women, adolescents, children, athletes and other potentially sensitive sub-populations. FSANZ found no scientific basis for setting a lower level of caffeine intake for adolescents on a body weight basis, than that applicable to adults. Metabolism and clearance of caffeine by adolescents is at least as rapid as in adults (see section 2.2.3.2). Differences in body weight between adolescents and adults are unlikely to result in significant health outcomes. FSANZ found little substantiated evidence that adolescents are regularly consuming caffeine in excess of 5.7 mg/kg bw/day (see SD1 of the 1st CFS). Tea and coffee and coffee substitutes and soft drinks contributed to the majority of caffeine intake in adolescents (see SD 2 of the 1st CFS). FSANZ has reviewed the study provided by the submitter[1] and notes that the study is not based on a nationally representative population and that protein powders do not typically contain caffeine. The proposed

Comment	Raised By	FSANZ Response
supplements such as protein powders with a recent Australian study finding 49.8% of 14-16 year old boys reported current use of protein powders and 62% had intentions to use protein powders. Whilst it is unknown the extent these products contained caffeine; it is common practice for such products to contain caffeine. Users of sports foods commonly 'stack' with other products which creates a potential risk of excess caffeine consumption in this vulnerable age group.		permission would see a maximum one-day quantity limit that could be used in protein powders, but that product would then need to comply with labelling statements for a FSSF containing caffeine. [1] Muscle building supplement use in Australian adolescent boys: relationships with body image, weightlifting, and sports engagement - PubMed)
Does not agree there should be a 'preferred approach'. The current regulations do not allow for future product development needs. Recommend a separate sports nutrition caffeinated supplement category in the Code which would enable development of pre-workouts safe for the targeted adult consumer. Stated that caffeinated pre-workouts and drinks should only be sold to adults. Consumers should be free to make their own decisions as long as the product contains less than 600 mg of caffeine, the level that the TGA has considered to be a therapeutic dose level. Labels should be clearly labelled for consumer education.	ATP	FSANZ expects this proposal to result in a net improvement on FSSF product development. There is currently no explicit permission in the Code for the addition of caffeine to FSSF. The proposed permission gives regulatory clarity to both industry and regulators and enables manufacturers to confidently and safely add caffeine up to a 200 mg one-day quantity of caffeine. This may lead to more investment in the sector, leading to greater product development. FSANZ appreciates that this puts a limit on the amount of caffeine permitted in FSSF, however this level is supported by FSANZ's assessment as a safe and suitable amount of caffeine to permit in FSSF when also considering additional caffeine consumption throughout the day such as from tea or coffee. The Therapeutic Goods (Poisons Standard – June 2024) Instrument 2024[20], lists caffeine in Schedule 4 as a prescription-only medicine for internal human therapeutic use in divided preparations with a maximum recommended daily dose of greater than 600 mg total caffeine or in undivided preparations with a concentration of greater than 5% with a maximum recommended daily dose of greater than 600 mg caffeine. These requirements relate to a therapeutic use of caffeine and are different to those for a maximum permitted quantity in food. FSANZ's safety assessment did not identify a need to limit the sale of caffeinated FSSF to adults only. Regarding the sale of caffeinated pre-workouts only to adults, FSANZ's safety assessment found that a single acute dose up to 200 mg in FSSF does not pose a risk of acute

[20] Federal Register of Legislation - Therapeutic Goods (Poisons Standard—June 2024) Instrument 2024

Comment	Raised By	FSANZ Response
		poisoning to adolescents, see section 2.2.3 of this report.
The 200 mg limit is lower than other markets in the world (provided examples of the Health Canada Natural Health Product Workout Supplements Monograph, EFSA, USA FDA/IOM). And notes that the 400 mg daily limit is based on a 70 kg adult consuming 5.7 mg/kg caffeine per day. However, an adult bodyweight of 70 kg is not reflective of the average weight of female and male Australians i.e., 72 kg and 87 kg, respectively (ABS, 2018). When based on the average weight of Australians, the 5.7 mg/kg/day maximum limit, this provides a higher daily limit of caffeine than the established maximum safe limit of 400 mg a day caffeine (as per the table provided).	THG	See Attachment 2 of the 1st CFS (FSANZ 2022) for FSANZ's discussion on alignment with international regulations. Caffeine regulations currently differ between countries and there is no international Codex standard or consistency across different countries. However, FSANZ's safety assessment aligns with those completed in comparable countries. FSANZ has proposed a regulatory response that is appropriate to protect the health and safety of the Australian and New Zealand populations. FSANZ appreciates that there may be individuals who can tolerate higher acute doses of caffeine due to a higher body weight, however the 200 mg limit considers additional factors such as potential ergogenic effect (see Appendix 2 of this report) and consumption of caffeine via non FSSF sources. FSANZ therefore considers a maximum one-day quantity of 200 mg appropriate for FSSF.
The following submitters provided comments on FSANZ's Risk Assessment		
These submitters noted the limitations of FSANZ's dietary intake assessment with the following comments (not all of the topics below are necessarily the representative view of all the submitters listed): One submitter did not consider that more up-to-date consumption data would affect FSANZ's overall proposed regulatory approach. Specific issues that were raised were (not all of the topics below are necessarily the representative view of all the submitters listed): • Conclusions on caffeine consumption were drawn from surveys conducted in 2011-2012 (Australia) and 2008 in (NZ) and with no children included in the 2008 New Zealand Survey.	AFGC, NZFGC, DA, VIC DoH and DEECA, NZFS	The best available caffeine concentration data were drawn from the databases used in the 2011-12 National Nutrition and Physical Activity Survey and 2008 New Zealand Adult Nutrition Survey. Changes in Australian and New Zealand food and beverage consumption patterns and caffeine intakes resulting from changes to the food supply will be reflected in future national nutrition surveys, such as that included in the Intergenerational Health and Mental Health Study currently underway in Australia. This will include the consumption of products new to the market since previous surveys. Where relevant, these data were updated to reflect more recent data from Australian and New Zealand food composition databases, food labels and product websites. The dietary intake assessment has been supplemented with more recent evidence from a social science assessment as outlined in section 2.1.2 to provide another source of evidence These data were the best available evidence. No new consumption data were provided by submitters and no newer nationally representative

Comment	Raised By	FSANZ Response
• Old data means all that can be concluded is non-alcoholic beverages particularly tea and coffee were the main contributors to caffeine intake. • New consumption data would provide an insight as to whether stacking remains an issue. • Possibly underrepresents the dietary caffeine intakes of 13–19-year-olds (no new data provided by submitter). • Significant increase in the availability of caffeinated beverages since the 2011-12 NNPAS. • Increase in the availability and promotion of caffeinated sports supplements (no data provided). • FSANZ should consider new studies and surveys on assessing the indirect health issues associated with a change in consumption patterns towards energy drinks, frappes and syrups rather than or in addition to coffee and tea. • Future national nutrition survey data could be used by FSANZ to inform the premarket assessment of any future applications seeking to amend the Code to add caffeine. • Some non-cola soft drink products are positioned as FCBs, which they assume makes use of the caffeine permission, but do not contain any listed substances permitted in FCBs. Considers this may be an unintended use of the FCB provisions and that a dietary intake assessment may not capture the potential increase in caffeine intake through this use.		consumption data are available. Note that under Standard 2.6.4 – Formulated caffeinated beverages, a FCB **must** contain caffeine and **may** contain other specified substances (listed substances) and otherwise comply with Standard 2.6.4.
Stated that FSANZ found little evidence that anyone other than 15% of pregnant/lactating women were exceeding recommended daily levels. The details regarding other population groups (including athletes) were uncertain due to the lack of nationally representative consumption data (especially specifically on athletes and sports foods). FSANZ found no evidence of the food source of accidental or malicious caffeine poisoning of children under five years so a prohibition seems unnecessarily excessive and will not address accidental or malicious toxicity. Further targeted	NZFGC	In proposing a general prohibition, FSANZ considered a range of evidence beyond reports to poison centres, including 33 research reports that examined how consumers are consuming caffeine (see SD 3 – social science literature review) (FSANZ 2022d). The social science literature review found that 14-33% of the general population may be regularly exceeding recommended daily limits of caffeine. These studies were published between 2017 and 2020 and therefore complement FSANZ's dietary intake assessment based on earlier data (2011-2012 and 2008-2009 in Australia and New Zealand, respectively). The proposed approach is intended to assist in the prevention of more

Comment	Raised By	FSANZ Response
research or evidence beyond reports to poisons centres is required. Strongly recommended that poisons centre data for the next five years is analysed and if there is no change in the number of reports, the prohibition is reviewed and removed.		caffeine entering the food supply, especially highly concentrated forms of caffeine, which can pose a health and safety risk to consumers. Under this approach, permission to add caffeine would be considered on a case-by-case basis through an application to FSANZ to amend the Code. For more detail on FSANZ's rationale for a general prohibition, see sections 2.2 and 2.2.1.2. Poison's information data is not used by FSANZ for quantitative risk assessment purposes, instead it provides some contextual information that contributes to FSANZ's weight of evidence assessment. FSANZ considers that new Poison's Centre data are unlikely to provide grounds for a review of the proposal.
The 2018 Australian Secondary Schools Diet and Activity survey found most adolescents were not consuming energy drinks (approx. 8% regularly) however regular consumption more common in males. The Australian Secondary Schools Alcohol and Drug Survey was in the field in 2022. FSANZ could consider accessing data around energy drinks to provide further analysis of this trend as more recent data from overseas on energy drink consumption in this age group is significantly higher (ranging from 30-50%) (De Sanctis et al, 2017).	TAS DoH	Evidence from the 2018 Australian Secondary Schools Diet and Activity survey was included in SD 3 (pages 18 to 22 – see Nuss et al., 2021). The 2022-23 Australian Secondary School Students Alcohol and Drug Survey has not reported data on energy drink consumption, except where mixed as an alcoholic beverage.
Noted the scope of the literature review was relatively narrow with a focus on the effect of caffeine intake on time-trial performance in sports. In the literature review on sports performance and caffeine, it states that research published after August 2017 was not included due to the method of study selection. Suggested it is stated up front in the report (currently in the appendix to SD4). Considered there are other benefits to including an updated search (Aug 2017-~2022) such as newer studies may alleviate some of the identified limitations (indirectness, risk of bias).	NZFS	The scope of the nutrition assessment on the effects of caffeine on exercise performance was restricted to time trial performance in swimming, running, cycling and rowing. Although time trials are a valid surrogate for exercise performance, they do not represent all types of exercise performance, however the limited scope was necessary due to the high volume of publications relating to caffeine and exercise performance. Similarly, the scope was limited to relevant studies cited in a 2020 umbrella review (Grgic et al. 2020). The current assessment of the body of evidence was downgraded for indirectness due to the limited scope of time trials in four sports, as well as the studies predominantly being undertaken in young adult males who were trained athletes with high aerobic capacity, and not the general Australian and New Zealand population (including females and other age groups), untrained or unfit individuals undertaking sport, or

Comment	Raised By	FSANZ Response
		sports where outcomes cannot be predicted by time trials. Including studies published since 2017 would be unlikely to alter the issue of indirectness as exercise performance trials are rarely undertaken on the general Australian and New Zealand populations. Similarly, a small number of additional studies cannot negate the risk of bias in the included studies.
It would be helpful to explain (in section 1.4.6 of the 1st CFS) the implications of the limitation indirectness i.e., that the true effect may be different than the estimated effect for groups that were minimally represented in the studies such as women and non-trained people. This is relevant because it is possible that more recent studies may address this limitation.	NZFS	Indirectness refers to how well the evidence included in the review answers the question posed – does caffeine improve exercise performance in Australian and New Zealand populations. The outcomes in the review indicate that caffeine improves exercise performance in young male athletes, but the results of the review are not certain for the broader Australian and New Zealand populations. The issue around recent studies changing indirectness is discussed above.
Noted work from the US National Health and Nutrition Examination Survey (NHANES) which provides some evidence that dietary intake patterns of caffeinated beverages did not substantially change between the years of 2013 and 2016. The percentage of energy drink consumers remained relatively low in the overall population, and amongst children. Hourly and daily patterns of consumptions showed no clustering of caffeinated beverage consumption events over short periods.	NZFS	FSANZ notes this comment.
At the 1st CFS, FSANZ proposed a regulatory approach only and did not provide drafting options in the Code. *The following submitters provided suggestions for drafting of the proposed amendment in both FSSF and general foods.*		
• The definition of FSSF currently relates to a nutritional or performance goal (FSANZ 1st CFS pg. 28). Given caffeine will be a voluntary ingredient, defining the purpose of caffeine in FSSF becomes necessary to determine how it is listed in Schedule 29. FSANZ's description of a biologically active substance (BAS) in determining whether listing in the NIP is necessary (1st CFS pg. 32) implies caffeine is a BAS when used in FSSF. If correct, listing as a BAS does not define the purpose of addition. Given	NSWFA	As noted above, FSANZ has demonstrated an ergogenic benefit of caffeine by a scientific assessment, hence its permission in FSSF is performance related. It is however proposed by FSANZ that the one-day quantity permission in FSSF is placed in Standard 2.9.4, rather than Schedule 29 of the Code, which means defining the function of caffeine (e.g. as food additive or nutritive substance) in a FSSF in the Code is not needed (see the draft variation at Attachment A). The proposed 200 mg one-day quantity in FSSF includes caffeine from all sources including caffeine naturally present in plant sources of caffeine. In other words, manufacturers will only be permitted to add a

Comment	Raised By	FSANZ Response
FSANZ has determined caffeine has a beneficial ergogenic effect, it may be interpreted that caffeine when added to FSSF is not providing a nutritional effect, it is performance related. • This separation of function has implications for the 200 mg caffeine ceiling so that it considers all caffeine containing components not just those intentionally added. • If caffeine however, has an ergogenic purpose, where does guarana extract sit within the Code compared with guarana berry (the extraction process will likely concentrate the caffeine content of guarana, above that occurring in the berry as harvested)? Appreciate further consideration on the operation of Chapter 1 definitions in the Code for the purpose of defining the purpose of concentrated, naturally occurring caffeine sources when sold as foods or used as ingredients.		total of 200 mg per one-day quantity regardless of the source. See Appendix 1, Item (5) relating to paragraph 2.9.4—3(2)(b) which refers to permitting 200 mg caffeine 'in total, from any source' and see section and 2.2.5).
• Suggest another express prohibition in Standard 1.1.1—10 that inserts *(k) caffeine* into clause (6). The amendment should regulate beverages such as flavoured soft drinks (non-cola) using caffeine in the drink as a 'stimulant' and not as an additive, nutritive substance or novel food ingredient. • Changes to Standard 1.1.1 will require good communication with industry.	SAH	The proposed amendment is in alignment with the suggestion from SAH and would prohibit the addition of caffeine to beverages such as flavoured soft drinks (that are non-cola and not FCBs).
Suggested that amendments to sections 1.1.1—10(5) and (6) be considered as part of P1056 so the prohibition applies to both the retail sale of caffeine as food and to the use of caffeine as an ingredient or component of another food for retail sale to remove regulatory ambiguity. Also suggested that operation of subsection 1.1.1—10(7) is removed for the purposes of the 200 mg maximum one-day quantity of caffeine. This provides for continued permission of caffeine in foods from naturally occurring sources but capped at a maximum level of 200 mg per one-day quantity.	NSWFA	Refer to above response, outlining how FSANZ is proposing to amend the Code.

Comment	Raised By	FSANZ Response
So that: • Caffeine will not be able to be sold as food for retail sale without express permission. • Caffeine will not be able to be added to another food for retail sale as an ingredient or component without express permission. • Where permitted, in any food or as a food caffeine will be subject to a maximum 200 mg one-day quantity. • The 200 mg one-day quantity limitation will apply to total caffeine in all individual foods for retail sale regardless of the source. No food for retail sale may contain more than 1% caffeine (liquid) or 5% (solid) caffeine. This would resolve regulatory ambiguity as well as identify those products consumed for the sole purpose of supplying large acute doses of caffeine to the body, which are therapeutic goods.		
In the 1st CFS, section 1.5.4, FSANZ outlined the requirements of section 7 of the TG Act and that the provisions of the FSANZ Act and the Code do not apply to therapeutic goods that contain caffeine. *The following submitters provided comments on this topic.*		
The limits for caffeine introduced by the TGA are sufficient to address risks from pure and highly concentrated caffeine products that are not foods.	SAH	FSANZ notes this comment.
Greater consistency is needed between FSANZ and the TGA on caffeine levels in products for oral consumption. The TGA indicates for listed medicines the maximum recommended daily dose must not provide more than 400 mg of total caffeine from all ingredient sources, whereas FSANZ is proposing a permission of total caffeine up to a maximum of 200 mg in a 'one day quantity' in conjunction with appropriate labelling requirements. There is a lack of consistency in messaging.	DA	The regulatory arrangements for foods and therapeutics serve different purposes and therefore it is not necessarily expected they would be aligned. The proposed caffeine limits and labelling for FSSF take into account that consumers may consume caffeine from other food sources in addition to the 200 mg from a FSSF.
In the 1st CFS, sections 1.5.6, 3.5.3 and Attachment 2 discussed the proposed approaches in general foods and FSSF and alignment with international regulations.		

Comment	Raised By	FSANZ Response
The following submitters commented on this topic.		
FSANZ should consider caffeine at a daily allowance of 400 mg/day in FSSF products. The FDA, Health Canada and EFSA have all determined that a total daily intake of 400 mg of caffeine is unlikely to pose a risk of serious harm to the general population of adults unless pregnant (where it should be 200 mg/day). This aligns with the medical literature quoted in submission. Stated that 500 mg is commonly found in Australian manufactured and sold pre-workout drinks if they are double scooped. Argues there is no evidence this dose is problematic. Believes that a reduction in caffeine per serve will see gym goers taking more scoops, thus ingesting more of the other active ingredients or directly importing American pre-workouts, which may include other banned substances. This harms Australian businesses and exposes more Australians to pre-workout products with undisclosed amount of caffeine and other stimulants. A huge number of caffeinated sports products delivered from overseas harms Australian businesses.	ATP	Currently there is no express permission for caffeine in FSSF and thus FSANZ is proposing a change that would provide greater regulatory clarity for manufacturers and regulators. FSANZ's assessment concluded that chronic, moderate consumption of caffeine in foods by adults is safe up to 400 mg/day and that adverse effects can occur in a single serve of caffeine over 210 mg. This aligns with other international findings, as noted by the submitter. FSANZ proposes to explicitly permit in FSSF, total caffeine up to a maximum of 200 mg in a one-day quantity. In conjunction with the mean caffeine intake from all other food sources, total intake is not expected to exceed the recommended maximum daily limit of 400 mg/day for consumers who are using FSSF in accordance with the directions on the label. In addition, FSANZ found there is limited evidence that increasing intake over 3 to 6 mg/kg bw has a better effect on exercise performance. The *Imported Food Control Act 1992* requires all food imported into Australia to be safe and to comply with the standards that comprise the Code. 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. It is not clear that the proposed approach will result in greater demand for imported products relative to domestic products. FSANZ is not aware of any evidence to suggest a significant number of consumers will turn to other markets as a result of this proposal. FSANZ is aware that there are imported products that are on the Australian and New Zealand market that may compete with domestically manufactured products. The proposed voluntary permission will, however, allow better opportunities for domestic manufacturers, as it will provide certainty to them that caffeine would be explicitly permitted up to a specific amount in FSSF.
In the 1st CFS, FSANZ asked the following question: ***Do you foresee any compliance or enforcement issues with the preferred approach of expressly permitting total caffeine in FSSF at a maximum one-day quantity of 200 mg, whilst expressly prohibiting the addition of caffeine to all foods apart from cola-type drinks and FCBs?***		

Comment	Raised By	FSANZ Response
The following submitters provided comments on enforcement and compliance of the proposed approach.		
Not aware of any compliance or enforcement issues posed by the preferred approach noting (not all of the topics below are necessarily the representative view of all the submitters listed): • the proposed approach will provide regulatory certainty • the food supply will still reflect naturally occurring caffeine through the addition of chocolate and other ingredients which naturally contain caffeine.	AACS, ABCL, Frucor, NZBC, AFGC, NZFGC	FSANZ notes these comments.
The maximum one-day amount needs to incorporate the total caffeine from all sources. Enforcement officers have noted that some foods will list the extracts (e.g., guarana, kola nut, yerba mate, cocoa beans) but not declare the active substance. This makes it very challenging to enforce.	QLDH	Refer to above response outlining how FSANZ is proposing to amend the Code. The proposed 200 mg one-day quantity in FSSF includes caffeine from all sources including caffeine naturally present in extracts. In other words, manufacturers will only be permitted to add a total of 200 mg caffeine per one-day quantity regardless of its source and including caffeine that is naturally occurring. See Appendix 1, Item (5) relating to paragraph 2.9.4—3(2)(b) which refers to permitting 200 mg caffeine 'in total, from any source'.
Anticipate there will be existing FSSF products that do not comply with FSANZ's preferred approach. There may be an increased workload in the short term for jurisdictions and DAFF (imported food program) to assess compliance. This should in time result in greater regulatory certainty for both businesses and jurisdictions.	QLDH	FSANZ notes this comment. FSANZ is proposing a two-year transition period to allow time for compliance with the new requirements. See section 3.1 for further detail.
There are products in the marketplace that could encounter compliance issues containing upwards of 150 mg caffeine per individual serve. Is consideration being allowed for consumers who may consume multiple serves of these affected products per day? Note, this submitter does not foresee a compliance issue across their product range.	Aldi	FSSF must be labelled with directions stating the recommended amount and frequency of consumption of the food. Under the proposed approach, for FSSF containing caffeine, these instructions should direct consumers to only consume a maximum of 200 mg total caffeine in one day from a single serve or through multiple serves of the FSSF.

Table E: FSSF – Other issues raised – submitter comments and FSANZ responses

Comment	Raised By	FSANZ Response
In the 1st CFS, FSANZ discussed evidence of stacking behaviours in some parts of the population (section 2.3.3.6).		

Comment	Raised By	FSANZ Response
The following submitters commented on this topic.		
A range of comments were received including (not all of the topics below are necessarily the representative view of all the submitters listed): • Recommended FSANZ explore a prohibition of 'stacking' for highly caffeinated products via amending Standard 1.1.1—10(9) with an information requirement to prohibit advertising and marketing practices on stacking of all food for retail sale with caffeine amounts in excess of 100 mg per one-day quantity or where the combined total of caffeine per one-day quantity from all foods in the 'stack' exceeds 200 mg per one-day consumption. • Concern with labels which suggest a double 'serve' and the practice of stacking, consider explicit prohibitions/warning statements. • Concern for health and safety of consumers of habitual caffeine who are also stacking FSSF. Caffeine clearance is slow (half-life of 5-6 hours). Even more prudent for caffeine sensitive individuals. • At the elite sporting level, Sports Dietitians Australia recommend athletes seek advice from an Accredited Sports Dietitian to determine the lowest effective dose of caffeine. • Promotion of double servings undermines the purpose of a one-day quantity.	NSWFA, Tas DoH, DA, VIC DoH and DEECA	FSANZ is proposing to explicitly permit a maximum one-day quantity of 200 mg caffeine in FSSF, to prevent manufacturers from recommending consumption of more than this amount. Under the proposed requirements, a manufacturer could not recommend consuming an amount of a FSSF that would result in consumption of over the 200 mg one-day quantity on the label of that FSSF. FSANZ is investigating the issue of stacking multiple serves or multiple sources of FSSF in one day through Proposal P1010. The preliminary assessment in P1010 has found limited evidence related to the stacking of FSSF and this limited evidence cannot be used to support regulatory change specific to caffeine. FSANZ will continue to consider the issue in Proposal P1010.
The following submitter commented on analogues and derivatives of caffeine in FSSF		
Does the 200 mg one-day quantity limit for FSSFs include only caffeine or will it also include related compounds including other methylxanthines? For example, how would the caffeine and other methylxanthines present in guarana be considered in FSSFs?	AIS	The 200 mg one-day quantity applies only to the chemical caffeine and not to related compounds. As outlined above, FSANZ is proposing that the total amount of caffeine from all sources will need to be declared in the NIP on a FSSF containing caffeine. Derivates of caffeine would continue to be regulated by the Code as they currently are, for example, as substances that require a pre-market safety assessment. If a manufacturer wishes to add a substance to FSSF (or any food for retail sale) that is not permitted, it would require an application to amend the

Comment	Raised By	FSANZ Response
		Code.
The following submitters commented on the interplay with the New Zealand Supplemented Food Standard and the TTMRA		
Noted the intent of the New Zealand Supplemented Food Standard (NZ SFS) is to provide an interim regulatory arrangement for supplemented food until there are appropriate provisions in the Code. This submitter understands that the outcomes of P1056 (once gazetted) into the Code would result in the review of corresponding caffeine provisions in the NZ SFS. NSW would appreciate some commentary on this matter in the 2nd CFS.	NSWFA	The comment is noted. The operation of the NZ Supplemented Food Standard (2016) is outside of FSANZ's remit and is therefore out of scope for P1056. See sections 1.4.3 and 2.4.1.3 for detail on how the proposed amendments would impact New Zealand standards.
Noted the NZ SFS currently permits supplemented food to contain caffeine for a purpose other than a food additive. An advisory statement and nutrition information must be provided on the label of a supplemented food if the food contains a greater level of caffeine than is required to achieve a technological function under conditions of Good Manufacturing Practice. Also noted that while the NZ SFS does not currently specify a maximum permitted level for caffeine in supplemented foods, the current provision in Standard 1.1.1—10(5)(g) of the Code applies to supplemented foods. NZFS are currently considering the implications of the regulatory measures proposed under this proposal on the current caffeine provisions in the Supplemented Food Standard.	NZFS	FSANZ notes these comments.
Noted there are products on the market presented as FCBs but promoted as 'providing energy for sporting activities' available from some online stores in Australia containing over 200 mg per serve and greater than the permissions in FCBs. These products are imported into Australia via New Zealand under the TTMRA and purported to be formulated to comply with the NZ SFS, P1056 should provide greater legal clarity for businesses and enforcement agencies on these types of products.	QLDH	FSANZ appreciates that there are supplemented food products on the Australian market that are not regulated under the Code, however the NZ SFS and its operation is outside of FSANZ's remit and is therefore out of scope for P1056. The *Imported Food Control Act 1992* (IFC Act) requires all food imported into Australia to be safe. 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.

Table F: Labelling – submitter comments and FSANZ responses

Comment	Raised By	FSANZ Response
In the 1st CFS, FSANZ proposed to require an advisory statement on all FSSF. In section 3.2.1.8.1 the proposed approach was as follows: • ***FSANZ proposes to require an advisory statement using wording to the effect of 'contains caffeine' on the label of all FSSF containing caffeine, irrespective of the source or amount.*** • ***For FSSF not required to bear a label under Standard 1.2.1, FSANZ is proposing to require the advisory statement to be provided either in connection with the sale of the food or upon request, for example, on a sign or verbally if asked.*** • ***The actual wording of the advisory statement on the label would not be prescribed.*** • ***This requirement would be consistent with the advisory statement currently required on other foods with specific permission to contain added caffeine, such as cola-type beverages and FCBs.*** *The following submitters provided comment.*		
The evidence presented in P1056 indicates that the average consumer does not know how much caffeine is in foods and beverages, how much is safe to consume, or the risks of overconsumption. This poses a risk to public health and safety. The 'contains caffeine' label may have minimal impact without a better understanding of cumulative caffeine consumption levels. This issue is best addressed through consumer education.	AACS	It is proposed that the addition of caffeine to foods is prohibited unless specifically permitted. The cumulative effects of caffeine consumption have been taken into account in determining compositional limits in FSSF. Caffeine has been present naturally in certain foods for many years and it is proposed that the addition of caffeine to certain foods only, is subject to specific compositional limits as outlined in this report. Caffeine consumption via (e.g.) coffee and tea is generally self-limiting in adults, due to consumers' familiarity with its adverse effects (SD2). FSANZ is therefore not proposing any additional labelling for products that may contain caffeine except as outlined in this report (section 2.2.6). See section 3.2 regarding consumer education.
Supported FSANZ's approach to require an advisory statement using words to the effect of 'contains caffeine' on the label with the following comments (not all of the topics below are necessarily the representative view of all the submitters listed): • Supports the wording of the advisory statement to not be prescribed (allows flexibility for manufacturers, particularly for brands with smaller sized packaging). • Supports approach irrespective of source or amount. This is consistent with cola-type beverages and FCBs.	ABCL, Frucor, NZBC, AFCG, AIS, NSWFA, NZFS	FSANZ notes this support.

Comment	Raised By	FSANZ Response
There is merit in considering mandating the words 'contains caffeine' on caffeine containing foods so there is consistency in what is required on food labels to declare caffeine content.	NSWFA	Given the other risk management measures for FSSF including the requirement to declare caffeine content in the NIP and a warning statement directed at population groups at higher risk, for which the wording is prescribed, FSANZ does not consider there is a need to prescribe the wording of the advisory statement 'contains caffeine'.
Suggest that a mg threshold/range is considered and incorporated into any labelling amendments, due to flavouring agents that may contain extremely low amounts of caffeine and thus shouldn't require label advisory statements or a declaration of the caffeine content, incidentally, should the flavour be the only source of caffeine in the product.	THG	Refer to section 1.4.1 above. This explains that the only permission in the Code for caffeine as a flavouring is in cola beverages. Flavourings are regulated as food additives, and no other permissions exist for the use of caffeine as a food additive (flavouring).
In the 1st CFS, section 3.2.1.8.2 FSANZ proposed the following with regard to the declaration of amount of caffeine and one-day quantity: • ***A new requirement to declare the average quantity of caffeine present (from all ingredient sources) in any FSSF containing caffeine, irrespective of the source or amount.*** • ***Caffeine content must be declared in mg, on a per serving and per unit quantity (100 g or 100 mL) basis, in the NIP, following the entry for sodium, where other biologically active substances are required to be declared, if any.*** • ***For products requiring reconstitution with water, the declaration must be for the product following reconstitution.*** • ***The FSSF Standard currently includes requirements to label with directions stating the recommended amount and frequency of consumption of the food and a statement of recommended consumption in one day (section 2.9.4—4). Therefore, these instructions should not direct consumers to consume more than 200 mg per day of caffeine from the FSSF.*** • ***The proposed requirement to declare the average quantity of caffeine in the NIP would mean that such a declaration is not a nutrition content claim (subsection 1.1.2—9(2)).*** *The following submitters provided comment.*		
Supported the proposed new requirement to declare the average quantity of caffeine present in any FSSF containing caffeine. Submitters made the following comments (not all of the topics below are necessarily the representative view of all the submitters listed): • The labelling approach is appropriate. • Would help to educate consumers and assist poisons centre staff in making accurate risk assessments in exposure cases provided the dosages and amount of caffeine are clearly listed in mg, gm or mL of actual product.	ABCL, Frucor, NZBC, AFGC, AIS, NSWPIC, NSWFA, NZFS, SDA	FSANZ notes this support.

Comment	Raised By	FSANZ Response
• Understands this requirement would apply to the total caffeine content of the FSSF and not just to sources of added caffeine in FSSF. • Critical to aid in the protection of irresponsible consumers and vulnerable population groups including junior/younger individuals.		
If the nutrition information is to be listed as per dosage reconstituted with fluid, it needs to also specify the weight of FSSF powder added to a specific volume to reconstitute the dose.	NSWPIC	For products requiring reconstitution with water, the declaration in the NIP must be for the product following reconstitution, as currently required by section 1.2.8—11 of the Code. The label on the FSSF must include directions stating the recommended amount (and frequency) of intake of the food.
Suggest considering a further amendment to require caffeine to be declared in the NIP and not adjacent or following it as currently required for FCBs.	NZFS	The specific labelling requirements for FCBs were established under Application A394 as a risk management measure, in conjunction with a prohibition of nutrition content claims about vitamins and minerals. Under these requirements, compositional information, including caffeine and other substances such as vitamins, is required to be adjacent to or following the NIP (section 2.6.4—5 and S12—5 of the Code). At this stage, this approach is maintained in its entirety, noting the different purpose and regulation of FCBs compared to FSSF.
This submitter stated that given the high proportion of intentional and recreational misuse that already exists in cases of FSSF caffeine toxicity, they question the ability of improved labelling and dosage recommendation to impact the behaviour of misuse.	NSWPIC	Noted. FSANZ agrees that labelling alone cannot prevent misuse of a product. The proposed compositional requirements, in conjunction with the proposed labelling and packaging requirements, help to address the risk of consumption of unsafe amounts of caffeine from FSSF. See also section 3.2 for further discussion on consumer education.
FSANZ should consider a requirement that international products include caffeine content on the label rather than stating ‘proprietary blend’.	DA	Labelling requirements in the Code or the NZ SFS would apply to foods sold in Australia and New Zealand, including those imported from other countries.
Suggested one set of label advisory statements be implemented across all categories and that all labels must state the amount of caffeine per serve to ensure consistency across all food categories permitted to contain caffeine (particularly for cola drinks and FCBs).	THG	The need for, and content of, advisory statements is aligned with the potential risk posed by the product, in particular the permitted concentration of caffeine. FSANZ is therefore not proposing to develop one set of advisory statements to apply to all categories as suggested.
In the 1st CFS, section 3.2.1.8.3 FSANZ proposed the following with regard to other advisory and warning statements:		

Comment	Raised By	FSANZ Response
• ***FSANZ is not proposing to require a warning or advisory statement for FSSF containing added caffeine specifically for lactating women and individuals sensitive to caffeine.*** *The following submitters provided comment.*		
Supported proposed approach.	ABCL, AFCG, Frucor, NZBC	FSANZ notes this support.
Did not support this approach with the following comments (not all of the topics below are necessarily the representative view of all the submitters listed): • Lactating women and individuals sensitive to caffeine should be included on the advisory statement consistent with FCBs, FSSF dose is higher than most FCBs, it is consistent with the *Policy Guideline - regulatory management of caffeine in the food supply* e.g. FSANZ should consider vulnerable populations, FSANZ's SD1 concluded the safe level of caffeine consumption is lower than the general adult population in these vulnerable populations. • FSANZ should consider statement design and placement. • Should expand statement to include adolescents (noting Poland's Sports Minister has just presented a bill that would ban the sale of energy drinks to those under 18 years of age. Threshold for caffeine consumption in adolescents is 100 mg/day). • Risk to adolescents requires further consideration in alignment with the policy guideline.	NSWPIC, DA, NSWFA, VIC DoH and DEECA	FSANZ has decided to include lactating women in the warning statement for FSSF containing caffeine, but not individuals sensitive to caffeine. See section 2.2.6 of this report for detail. FSANZ has had regard to the policy guideline in developing this proposed approach. In particular, a risk analysis has been undertaken considering the general population and taking into account vulnerable population groups including children, adolescents, pregnant and lactating women and caffeine sensitive consumers. FSANZ is not proposing to prescribe the design/format and placement of the FSSF warning statement, aside from the existing font size requirement in the Code, consistent with the current approach for the regulation of warning statements more broadly in the Code. See also response regarding adolescents above.
Noted on SD1 page 4 'Conclusions', it states there is insufficient evidence to provide recommendations to breastfeeding women. This could be inconsistent with statement later in the SD (section 2.6.3.3), it is recommended that women in the perinatal period should continue caffeine intake to avoid withdrawal symptoms.	NZFS	The text has been modified to clarify the advice for breastfeeding women. The modification is in the document 'P1056 2nd CFS Safety Assessment SD1'.
Stated there is an increased risk of caffeine toxicosis in population subsets who are prone to chronic/acute caffeine consumption, such as athletes and bodybuilders (although the	AACS	FSANZ notes this comment.

Comment	Raised By	FSANZ Response
extent of this problem in Australia and New Zealand is unclear due to insufficient data).		
For healthy adults, caffeine consumption has been shown to be relatively safe at a threshold of approximately 400 mg/day (and 100 mg/day in healthy adolescents). However, there may be vulnerable populations (i.e., pregnant women, children, individuals with cardiac or vascular disease) and individuals (i.e., the elderly or individuals with underlying medical conditions), who are not part of any vulnerable population but who, for genetic or metabolic reasons, may be susceptible to harmful effects from caffeine.	DA	FSANZ notes this comment. The approach proposed by FSANZ is intended to protect individuals susceptible to harmful effects from caffeine.
In the 1st CFS, sections 3.2.1.8.4 and 3.2.1.8.5 FSANZ proposed the following with regard to other advisory and warning statements: • ***Assuming caffeine is a 'biologically active substance', the existing conditions for making nutrition content claims about biologically active substances would apply to claims about the presence or absence of caffeine on FSSF. The proposed advisory statement 'contains caffeine' and the proposed declaration of caffeine in the NIP would not constitute nutrition content claims as these would be mandatory requirements and therefore not claims.*** • ***FSANZ is not proposing to make any amendments to the current provisions in the Code for claims as they apply to FSSF via this proposal.*** *The following submitters provided comment.*		
These submitters supported FSANZ's proposal to not amend the current provisions relating to nutrition content claims about caffeine, or health claim permissions existing in Standard 2.9.4 as it relates to FSSF containing caffeine. Believe there is strong evidence associated with caffeine and enhanced sports or exercise performance that could substantiate a health claim. They agree with FSANZ's approach to review the regulation of such health claims for FSSF under Proposal P1010 and will provide comments to FSANZ in that regard.	ABCL Frucor NZBC	FSANZ notes this comment.
This submitter notes FSANZ commentary that health claims concerning enhanced athletic performance in relation to caffeine content could not be made (CFS, pg. 33). FSANZ considers claims on FSSFs describing assistance in supplementing the diet with an energy source to be permissible. NSW requests further discussion on whether any	NSWFA	The regulation of claims including the suggestions from NSWFA will be considered and discussed in P1010 – Formulated Supplementary Sports Foods.

Comment	Raised By	FSANZ Response
claim concerning ergogenic effect could be construed as supplementing the diet with an energy source. Considered caffeine cannot be described as serving a nutritional purpose as ergogenic effects concern 'enhancing athletic performance'. There may be benefit in defining ergogenic in the Code. Suggested that definitions are required in the Code and clear advice is provided by FSANZ on the prohibition of use of certain words, on the label of FSSF in the 2nd CFS on the basis they are therapeutic claims. To ensure consumer and industry certainty there may be merit in considering an approach to claims for FSSF in a manner similar to P1030 – Composition and labelling of electrolyte drinks, i.e. to permit a limited number of claims about specific matters and to not permit self-substantiation.		
Agrees with FSANZ's approach. For clarity, consider it important to note that the prohibition in section 2.9.4—7 applies to all health claims, including self-substantiated claims, if that is the intent. Considers it should be explicit in the Code whether claims for caffeine and health effects other than enhanced athletic performance or beneficial physiological effects are permitted. If not, FSANZ should provide justification, otherwise it could limit innovation and create questions around implementation.	NZFS	See above response.

Table G: Consumer awareness, education campaigns and new research – submitter comments and FSANZ responses

Comment	Raised By	FSANZ Response
In the 1st CFS, FSANZ proposed a hybrid approach to the risk management of caffeine in the food supply. This included regulatory options and non-regulatory options. This included: • ***leveraging consumer education materials on the risks of pure and highly concentrated caffeine products already on the FSANZ website including key messages that explain the specific risks identified for each at-risk sub-population*** • ***education materials that would provide information for parents and caregivers of infants and pre-schoolers.***		

Comment	Raised By	FSANZ Response
The following submitters provided comment.		
Supported consumer campaigns and/or noted willingness to partner with FSANZ on developing non-regulatory measures with the following comments (not all of the topics below are necessarily the representative view of all the submitters listed): • Noted that energy drink manufacturers have been at the forefront of responsible sales and marketing practices with a number of initiatives referenced. • NZBC provides helpful information on the Code provisions and caffeine comparison in non-alcoholic beverages. • Should include messages that explain risks for each sub-population, parents and caregivers and adolescents. • Resources should be developed on the dangers of 'stacking' and multiple serves. • Linnaean names for caffeine containing foods (especially guarana, matcha green tea, yerba mate, kombucha, dark chocolate). • Resource listing natural sources of caffeine and variance in the strength. • An electronic app: 'know your 400 mg' (note the caffeine informer website has a calculator which could be used as a starting point). • A dose dependent visual display for gyms and health clubs on caffeine toxicosis: symptoms linked to dose varying from mild to life threatening. • NSWFA has a number of communication channels on the health impacts of caffeine. Some of these reference FSANZ. If FSANZ updated its caffeine education, NSW would look to update its own material to amplify this advice. • Support a coordinated inter-agency consumer information campaign on safe caffeine consumption and targeted research on caffeine consumption across the ANZ population including as part of the upcoming Intergenerational and Mental Health Study.	ATP, TAS DoH, AFGC, DA, Aldi, NSWFA, NZBC, ABCL, Frucor, QLDH, VIC DoH and DEECA	FSANZ thanks submitters for these suggestions and will take them into consideration when developing consumer education about caffeine (see section 3.2 for more details). Note also, more recent data on the consumption of caffeinated food products by adolescents have been included in SD3 (pages 43 to 48).

Comment	Raised By	FSANZ Response
• FSSF should provide information and education as to how products should be made up to ensure maximum of 200 mg per day is being consumed. • Education on the recommended daily intake limit for caffeine (400 mg). • A study exploring the relationship between regular energy drink intake and sleep among adolescents demonstrated a negative correlation between energy drink consumption and meeting the recommended hours of sleep (in both males and females). Further education for children, parents and teachers about the potential health risks of energy drink consumption and association with sleep implications is needed.		
Supports targeted research of caffeine consumption across Australia and New Zealand to support P1010 review of sports foods.	AFGC	Changes in Australian and New Zealand food and beverage consumption patterns and caffeine intakes resulting from changes to the food supply will be reflected in future national nutrition surveys, such as that included in the Intergenerational Health and Mental Health Study currently underway in Australia. If any new consumption data become available before completion of this proposal, these will be considered in the assessment.
In the 1st CFS FSANZ asked the specific question: ***Do you consider there are risks to consumers from caffeine in the current market environment, under the current regulations? Please provide any evidence or relevant examples in detail to assist FSANZ in its assessment.*** *The following submitters provided responses.*		
Submitters responded to this question with the following comments (not all of the topics below are necessarily the representative view of all the submitters listed): • Agree there are risks for certain population sub-groups and those who are prone to chronic/acute caffeine consumption, e.g. athletes and bodybuilders. • Possible risk in weight management and exercise fields especially young people, people who are time poor and needing energy. • Some people do not seem to be aware of the dangers of caffeine.	AACS, Aldi, NZFS, ATP, SDA, NSWPIC	FSANZ notes it's proposed approach to prohibit caffeine in the food supply unless permitted, along with compositional limits where permitted, and specific labelling requirements as outlined in this 2nd CFS, would minimise the risks associated with consumption of caffeine above certain levels. FSANZ looks forward to the availability of the data/results from the next New Zealand National Nutrition Survey. FSANZ is investigating the issue of stacking multiple serves or multiple sources of FSSF in one day through Proposal P1010. The preliminary assessment in P1010 has found limited evidence related to the stacking

Comment	Raised By	FSANZ Response
• FSANZ's SD1 suggests that the safety of caffeine is related to public health/perceptions including a belief that the desired effects can be enhanced by unlimited increases in dose. Any upward trend in this should be monitored and if increasing, may require reconsiderations of the Standard and/or partnering with public health agencies to develop appropriate messaging. • Planning for the next NZ National Nutrition Survey is underway and will gather data on caffeine consumption in the NZ population aged two and above. FSANZ should specifically consider daily caffeine intakes per day and body weight. • No risks for consumers as caffeine is widely consumed and generally thought to be safe in moderate amounts (i.e. ≤ 400 mg/day) and a half-life of 3-7 hours. People who have suffered from toxicity have taken doses much larger than those currently in FSSF and often back-to-back. People who are caffeine sensitive have clear access to labels to indicate the amount of caffeine in relevant products. • Primary risk is 'stacking' of caffeine products (and highest for non-informed consumers) such as pre-workout supplements, often self-regulated via manufacturer's scoops. • Information provided during the poison centre calls often shows a lack of understanding about maximum or recommended doses. Impacts people's ability to self-regulate caffeine use with FSSF and energy drinks.		of FSSF and this limited evidence cannot be used to support regulatory change specific to caffeine. FSANZ will continue to consider the issue in Proposal P1010.
Questioned why FSANZ was defying medical literature and other health authorities and restricting caffeine to levels that are unlikely to have the desired effect, which begins significantly at 250 mg. Should restrict daily levels to 400 mg/serve once daily and clearly label the levels to inform consumers.	ATP	See comments above regarding FSANZ's assessment of the evidence on the safety and benefits of caffeine in sports foods and on manufacturer and importer responsibilities.
In the 1st CFS FSANZ asked the specific question: ***Can you share any further knowledge of current research about:***		

Comment	Raised By	FSANZ Response
a. the health effects of caffeine, ***b. global developments in caffeinated food products, or*** ***c. regulatory approaches being taken in comparable markets?*** *The following submitters provided responses.*		
These submitters provided references to research articles in their submissions relating to safe caffeine intake, stacking, energy drink consumption in adolescents, caffeine toxicity, Euromonitor reports, vulnerable populations, possible relationships with bone health, sleep, side effects in sport, recent restrictions, international regulations and toxicosis case studies. See individual submissions for references.	DA, ATP, NZFS, AIS, WADoH	FSANZ thanks submitters for these references. FSANZ considers that no change is needed to the safety assessment based on these references.

Appendix 2 Ergogenic effects of caffeine: findings of peak bodies

International institution	Types of caffeine	Sports Involved	Dose	Ergogenic effects
European Food Safety Association[1]	Does not specify the type of caffeine.	Endurance sports.	Minimum 70 mg/dose of product. 3 mg/kg body weight (200 mg approximately), 1 h before physical exercise. 4 mg/kg body weight to reduce the perception of effort during exercise.	-Increases endurance performance. -Increases endurance capacity. -Reduces the perception of effort during exercise. These health claims were not on sports activity/sports people but on healthy individuals: -Increased alertness -Increased attention.
International Olympic Committee[2]	Anhydrous caffeine (pills or powder).	Endurance sports, intermittent sports, and short-term sprints sports.	3–6 mg/kg body weight, 60 min before exercise. >3 mg/kg body weight before or during exercise, accompanied by a source of CHO.	-Improves neuromuscular function. -Heightens the state of vigilance and alertness. -Reduces the perception of effort during exercise.
Australian Institute of Sports[3]	Caffeine (as in coffee and tea).	Endurance sports, team/intermittent sports, high intensity physical activity of short duration.	At 2–3 mg/kg body weight, benefits are observed.	-Directly contributes to optimal performance. -Stimulates the CNS. -Decreases the perception of effort during exercise.
Academy of Nutrition and Dietetics (American Dietetic Association)[4]	Does not specify the type of caffeine.	In its bibliographic references: endurance sports, intermittent sports, or team sports.	3–6 mg/kg body weight.	-Acts on the CNS, reducing the perception of fatigue. -Promotes the release of Ca^{2+} in the endoplasmic reticulum of skeletal muscle.

[1] Panel on Dietetic Products, Nutrition and Allergies (NDA). Scientific Opinion on the Safety of Caffeine. EFSA J. **2015**, 13. Available online: doi.org/10.2903/j.efsa.2015.4102

[2] Maughan, R.J.; Burke, L.M.; Dvorak, J.; Larson-Meyer, D.E.; Peeling, P.; Phillips, S.M.; Rawson, E.S.; Walsh, N.P.; Garthe, I.; Geyer,H.; et al. IOC Consensus Statement: Dietary Supplements and the High-Performance Athlete. Br. J. Sports Med. **2018**, 52, 439–455.

[3]Australian Institute of Sport (AIS). Australian Sport Commission. Classification. Available online: https://www.ais.gov.au/nutrition/supplements/group_a (accessed on 5 December 2024).

[4]Thomas, D.T.; Erdman, K.A.; Burke, L.M. Position of the Academy of Nutrition and Dietetics, Dietitians of Canada, and the American College of Sports Medicine: Nutrition and Athletic Performance. J. Acad. Nutr. Diet. **2016**, 116, 501–528.

Attachment A – Draft variations to the Australia New Zealand Food Standards Code

Food Standards (Proposal P1056 – Caffeine review) 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 the Delegate]

[Insert name 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 P1056 – Caffeine review) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

4. Transitional arrangements

(1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.

(2) During the transition period, a food product may be sold if the product complies with one of the following:

(a) the Code as in force without the variations made by this instrument; or

(b) the Code as amended by the variations made by this instrument.

(3) For the purposes of this clause, the transition period means the period commencing on the date of commencement of this instrument and ending 24 months after that date of commencement.

Schedule

Standard 1.1.1 Structure of the Code and general provisions

[1] Paragraph 1.1.1—10(5)(g)

Repeal the paragraph, substitute:

(g) if the food is for retail sale—caffeine.

[2] Paragraph 1.1.1—10(6)(j)

Repeal the paragraph, substitute:

(j) raw apricot kernels;

(k) if the food is for retail sale—caffeine.

Standard 1.1.2 Definitions used throughout the Code

[3] Subsection 1.1.2—2(3) (paragraph (e) of the definition of *warning statement*)

Omit '2.9.4—4(1)(a)(iii) or 2.9.4—4(1)(a)(iv)', substitute '2.9.4—4(1)(a)(iii), (iv) or (v)'.

Standard 2.9.4 Formulated supplementary sports foods

[4] Subparagraph 2.9.4—3(1)(c)(ii)

Repeal the subparagraph, substitute:

(ii) the amount of the substance added is no more than the amount specified in relation to that substance in Column 2 of the table; and

(d) caffeine.

[5] Paragraph 2.9.4—3(2)(b)

Repeal the paragraph, substitute:

(b) 95 mmol potassium; or

(c) 200 mg caffeine in total, from any source.

[6] At the end of section 2.9.4—3

Add:

(3) Caffeine must not be present in:

(a) a *formulated supplementary sports food in a powdered form at concentration of 5% or more; and

(b) a *formulated supplementary sports food in a liquid form at concentration of 1% or more.

[7] Subparagraphs 2.9.4—4(1)(a)(iii) and (iv)

Repeal the subparagraphs, substitute:

(iii) if the food does not contain caffeine—the *warning statement 'Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision'; and

(iv) if the food contains caffeine—the warning statement 'Not suitable for children under 15 years of age, or pregnant or breastfeeding women: Should only be used under medical or dietetic supervision'; and

(v) if the food contains added phenylalanine—the warning statement 'Phenylketonurics: Contains phenylalanine'; and

[8] After section 2.9.4—10

Add:

2.9.4—11 Formulated supplementary sports food containing caffeine – nutrition information panel

(1) The nutrition information panel for a *formulated supplementary sports food that contains caffeine must state the *average quantity of caffeine in:

(a) a *serving of the food; and

(b) a *unit quantity of the food.

(2) The information required in subsection (1) must be set out in the nutrition information panel:

(a) below the information about sodium required by subparagraph 1.2.8—6(1)(d)(iii); and

(b) above the information about any other nutrient or *biologically active substance required by subparagraph 1.2.8—6(1)(d)(iv).

2.9.4—12 Formulated supplementary sports food containing caffeine and comprised of small separate portions

(1) This section applies to a *formulated supplementary sports food that:

(a) contains more than 200 mg caffeine in total, from any source; and

(b) is sold in packaging that includes individual portions of the food; and

(c) any of the individual portions:

(i) are in a solid or semi-solid form (excluding powders); and

(ii) are not designed for individual sale; and

(iii) do not require further preparation before consumption.

Example: A formulated supplementary sports food sold in the form of chewables or dissolvable strips that contain caffeine.

(2) Each individual portion of the *formulated supplementary sports food referred to in paragraph (1)(b) must be separately packaged.

Schedule 9

[9] Section S9—2 (at the end of the table)

Add:

12	A formulated supplementary sports food that contains caffeine	the food contains caffeine.

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Proposal P1056 – Caffeine review) Variation

3. 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 P1056 to review permissions for caffeine in sports foods and in the general food supply; and consider the risk caffeine poses to sensitive sub-populations. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has prepared a draft variation – the *Food Standards (Proposal P1056 – Caffeine review) Variation.*

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared the draft variation to amend the Code to: prohibit a food for retail sale being caffeine or containing caffeine as an ingredient or component unless expressly permitted the Code; and to provide an express permission for formulated supplementary sports foods to contain caffeine, subject to compositional, labelling and packaging requirements, including the provision of advisory and warning statements. The aim is to address the risk caffeine poses to sensitive sub-populations including pregnant women, children and athletes. The draft variation also proposes other amendments to the Code as a consequence of the above proposed amendments.

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1056 will include two rounds of public comment following an assessment and the preparation of a draft variation and associated assessment summaries.

The first call for submissions was issued on 19 December 2022 and ended on 13 February 2023.

Following this second call for submissions, the Authority will consider whether to approve, amend or reject the draft variation, having regard to all submissions received.

The Office of Impact Analysis (OIA) has exempted FSANZ from the need to prepare a Consultation Regulation Impact Statement (CRIS) in relation to the regulatory change proposed (reference number OIA24-07750). The OIA was satisfied that the function of a CRIS will be achieved through the consultation undertaken by FSANZ under the FSANZ Act (which includes the preparation of this CFS and SD1). A Decision Regulation Impact Statement (DRIS) will be prepared by the Authority following the second call for submissions, and submitted to the OIA for assessment.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

References to 'the variation' in this section are taken to be references to the draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Proposal P1056 – Caffeine review) Variation*.

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation commences on the date of gazettal of the instrument.

Clause 4 provides a transitional arrangement.

8. Schedule to the variation

Standard 1.1.1 – Structure of the Code and general provisions

Items [1] and **[2]** of the Schedule to the variation propose amendments to Standard 1.1.1 of the Code.

Standard 1.1.1 contains (among other things) general provisions applying to the Code.

In particular, **items [1]** and **[2]** propose amendments to section 1.1.1—10,

Section 1.1.1—10 contains general requirements, including that food for sale must comply with any relevant compositional, labelling, information and packaging requirements in the Code.

The general compositional requirements in section 1.1.1—10 include what food for sale may / must not consist of, or have as an ingredient. For example, subsection 1.1.1—10(2) provides that subject to section 1.1.1—10, food for sale may consist of, or have as an ingredient, any food.

Item [1] would amend paragraph 1.1.1—10(5)(g) by repealing the paragraph and substituting it with an amended paragraph 1.1.1—10(5)(g). Amended paragraph 1.1.1—10(5)(g) refers to: 'if the food is for retail sale—caffeine.'.

Subsection 1.1.1—10(5) prohibits food for sale from being any of the food listed in the subsection—unless expressly permitted by the Code.

Currently, except where expressly permitted by the Code, paragraph 1.1.1—10(5)(g) prohibits food for retail sale in which caffeine is present at a concentration of:

- 5% or greater—if the food is a solid or semi-solid food; and
- 1% or greater—if the food is a liquid food.

If approved—the existing prohibition in paragraph 1.1.1—10(5)(g) would be amended so that food for retail sale must not be caffeine—unless expressly permitted by the Code. This is a new prohibition.

Item [2] would amend paragraph 1.1.1—10(6)(j) by repealing the paragraph and substituting it with an amended paragraph 1.1.1—10(6)(j) and a new paragraph 1.1.1—10(6)(k).

Subsection 1.1.1—10(6) prohibits food for sale from having, as an ingredient or a component, any of the food listed in the subsection—unless expressly permitted by the Code.

Existing paragraph 1.1.1—10(6)(j) is the last entry for subsection 1.1.1—10(6) and as such, the paragraph ends in a full stop.

To insert new paragraph 1.1.1—10(6)(k)—paragraph 1.1.1—10(6)(j) must be amended so it ends in a semi-colon (;) instead.

New paragraph 1.1.1—10(6)(k) refers to: 'if the food is for retail sale—caffeine.'.

If approved—the proposed amendment would prohibit all food for retail sale from having caffeine as an ingredient or a component—unless expressly permitted by the Code. This is a

new prohibition.

Standard 1.1.2 – Definitions used throughout the Code

Item [3] of the Schedule to the variation proposes an amendment to Standard 1.1.2 of the Code.

Standard 1.1.2 sets out definitions of terms used in the Code—unless the contrary intention is expressed elsewhere in the Code.
In particular, **item [3]** would amend paragraph (e) of the definition of *warning statement*) in subsection 1.1.2—2(3).

Warning statement is defined, for the purposes of food for sale as meaning a statement about a particular aspect of the food that is required to be expressed in the words set out in the provisions listed in the definition.

Item [3] would omit the reference to '2.9.4—4(1)(a)(iii) or 2.9.4—4(1)(a)(iv)', and substitute it with a reference to '2.9.4—4(1)(a)(iii), (iv) or (v)'.

This amendment is consequential to the amendment proposed in **item [7]**, which would amend existing requirements for warning statements in paragraph 2.9.4—4(1)(a); and add a new requirement for a warning statement (see below for details).

If approved, the effect of the amendment proposed in **item [3]** would be that the definition of *warning statement* in Standard 1.1.2 would include the new warning statement proposed in paragraph 2.9.4—4(1)(a).

Standard 2.9.4 – Formulated supplementary sports foods

Items [4]-[8] of the Schedule to the variation propose amendments to Standard 2.9.4 of the Code.

Standard 2.9.4 sets out compositional and labelling requirements for *formulated supplementary sports food*.

Formulated supplementary sports food is defined in subsection 1.1.2—3(2) as meaning a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals.

In particular, **items [4]** – **[6]** propose amendments to section 2.9.4—3.

Section 2.9.4—3 contains permissions and compositional requirements for formulated supplementary sports food.

According to subsection 1.1.1—10(3), food for sale must comply with any provisions of the Code relating to the composition of that kind of food (including provisions relating to the presence of other substances in that kind of food).

Item [4] would amend subparagraph 2.9.4—3(1)(c)(ii) by repealing the subparagraph and substituting it with an amended subparagraph (ii) and a new paragraph 2.9.4—3(1)(d).

Subsection 2.9.4—3(1) lists what formulated supplementary sports food may contain.

Existing subparagraph 2.9.4—3(1)(c)(ii) is the last entry in that list and as such, the subparagraph ends in a full stop.

To add new paragraph 2.9.4—3(1)(d) to that list—subparagraph 2.9.4—3(1)(c)(ii) must be amended so the subparagraph ends with '; and'.

New paragraph 2.9.4—3(1)(d) refers to: 'caffeine'.

If approved, the effect of the amendment proposed in **item [4]** would be that formulated supplementary sports food *may* contain caffeine in accordance with the Code i.e., the addition of caffeine in a formulated supplementary sports food by a food business would be voluntary.

However, if a food business adds caffeine to a formulated supplementary sports food—the food business would have to comply with the relevant compositional and labelling requirements in Standard 2.9.4 (see, for example, the new requirement proposed in **item [5]** below).

Item [5] would amend paragraph 2.9.4—3(2)(b) by repealing the paragraph and substituting it with an amended paragraph 2.9.4—3(2)(b) and a new paragraph 2.9.4—3(2)(c).

Subsection 2.9.4—3(2) lists what formulated supplementary sports food must not contain, in a *one-day quantity*.

One-day quantity, in relation to a formulated supplementary sports food, is defined in Standard 1.1.2 as meaning the amount of that food which is to be consumed in one day in accordance with directions specified in the label.

Existing paragraph 2.9.4—3(2)(b) is the last entry in that list and as such, the paragraph ends in a full stop.

To add new paragraph 2.9.4—3(2)(c)—paragraph 2.9.4—3(2)(b) must be amended so the paragraph ends with '; or'.

New paragraph 2.9.4—3(2)(c) refers to: '200 mg caffeine in total; from any source.'.

If approved, the effect of the amendment proposed in **item [5]** would be that if a food business adds caffeine to a formulated supplementary sports food—that food must not contain, in a one-day quantity, more than 200mg of caffeine in total.

'In total, from any source' refers to all caffeine permitted to be present in the food including caffeine that naturally occurs.

Item [6] would insert a new provision into section 2.9.4—3: subsection 2.9.4—3(3).

New subsection 2.9.4—3(3) prohibits the following formulated supplementary sports food from containing caffeine at or greater than the corresponding concentration levels:

- formulated supplementary sports food in a powdered form—5%;
- formulated supplementary sports food in a liquid form—1%.

The intent of new subsection 2.9.4—3(3) is to ensure that caffeine containing powdered forms of FSSF over 5% caffeine concentration and caffeine containing liquid forms of FSSF over 1% caffeine concentration are not sold as FSSF. These limits are commensurate with the safe maximum concentration limits identified in P1054.

This proposed new requirement must be read in conjunction with sub-paragraph 2.9.4—3(2)(c).

Item [7] proposes to amend section 2.9.4—4.

Section 2.9.4—4 contains labelling information requirements for formulated supplementary sports food.

According to subsections 1.1.1—10(8) and 1.1.1—10(9) of the Code respectively:

- if a labelling requirement of the Code applies to the sale of food, the labelling must comply with the requirement; and
- if an information requirement of the Code applies to the sale of food, the information must be provided as required.

In particular, **item [7]** would amend subparagraphs 2.9.4—4(1)(a)(iii) and (iv) by repealing the subparagraphs and substituting those paragraphs with subparagraphs 2.9.4—4(1)(a)(iii), (iv) and (v).

Existing subparagraphs 2.9.4—4(1)(a)(iii) and (iv) respectively set out the following mandatory warning statements for formulated supplementary sports food:

- the *warning statement* 'Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision'; and
- if the food contains added phenylalanine—the warning statement 'Phenylketonurics: Contains phenylalanine'.

Warning statement is defined in Standard 1.1.2 (see also **item [3]** above).

Amended subparagraph 2.9.4—4(1)(a)(iii) now refers to: 'if the food does not contain caffeine—the *warning statement 'Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision'; and'.

The warning statement itself is the same, but that statement would only be required if the formulated supplementary sports food does not contain caffeine.

If approved, amended subparagraph 2.9.4—4(1)(a)(iii) would require labelling for formulated supplementary sports food *that specifically does not contain caffeine* to contain the *warning statement*: 'Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision'.

Amended subparagraph 2.9.4—4(1)(a)(iv) refers to: 'if the food contains caffeine—the *warning statement 'Not suitable for children under 15 years of age, or pregnant or breastfeeding women: Should only be used under medical or dietetic supervision'; and'.

If approved, amended subparagraph 2.9.4—4(1)(a)(iv) would require labelling for formulated supplementary sports food *that specifically contains caffeine* to contain the *warning statement*: 'Not suitable for children under 15 years of age, or pregnant or breastfeeding women: Should only be used under medical or dietetic supervision'.

These new requirements are related to the proposed amendments to section 2.9.4—3 (see **items [4]** – **[6]** above).

New subparagraph 2.9.4—4(1)(a)(v) refers to: 'if the food contains added phenylalanine—the warning statement 'Phenylketonurics: Contains phenylalanine'; and'.

New subparagraph 2.9.4—4(1)(a)(v) is the same as existing subparagraph 2.9.4—4(1)(a)(iv), except that it has to be renumbered as a consequence of the other amendments proposed to

paragraph 2.9.4—4(1)(a) above.

If approved, the existing requirement for the labelling for formulated supplementary sports food that contains phenylalanine to contain the *warning statement*: 'Phenylketonurics: Contains phenylalanine' would continue to apply under new subparagraph 2.9.4—4(1)(a)(v).

The warning statements would have to be made in accordance with the Code (see, for example, the legibility requirements for warning statements in section 1.2.1—25).

Item [8] would insert two new provisions in Standard 2.9.4: sections 2.9.4—11 and 2.9.4—12.

New section 2.9.4—11 sets out nutrition information panel requirements specifically for formulated supplementary sports food that contains caffeine.

New subsection 2.9.4—11(1) requires the nutrition information panel for a formulated supplementary sports food containing caffeine to state the *average quantity* of caffeine in:

- a *serving* of the food; and
- a *unit quantity* of the food.

Average quantity, *serving* and *unit quantity* are terms defined in Standard 1.1.2 of the Code,

New subsection 2.9.4—11(2) specifies where the information required by new subsection 2.9.4—11(1) must be located in the nutrition information panel i.e.:

- below the information about sodium required by subparagraph 1.2.8—6(1)(d)(iii) of the Code; and
- above the information about any other nutrient or biologically active substance required by subparagraph 1.2.8—6(1)(d)(iv) of the Code.

According to subsections 1.1.1—10(8) and 1.1.1—10(9) of the Code respectively:

- if a labelling requirement of the Code applies to the sale of food, the labelling must comply with the requirement; and
- if an information requirement of the Code applies to the sale of food, the information must be provided as required.

Consequently, if approved, the effect of new section 2.9.4—11 would be that:

- the nutrition information panel for a formulated supplementary sports food containing caffeine would have to state the *average quantity* of caffeine in:
  - a *serving* of the food; and
  - a *unit quantity* of the food; and

- the above information would have to be located in the panel:
  - below the information about sodium required by subparagraph 1.2.8—6(1)(d)(iii) of the Code; and
  - above the information about any other nutrient or biologically active substance required by subparagraph 1.2.8—6(1)(d)(iv) of the Code.

Section 2.9.4—12 is a new provision that sets out a packaging requirement for formulated supplementary sports food that contains caffeine and comprises of small separate portions.

New subsection 2.9.4—12(1) sets out the formulated supplementary sports food to which the packaging requirement applies i.e., food that:

(a) contains more than 200 mg caffeine in total ('in total, from any source' refers to all caffeine
present in the food regardless of the source),
(b) is sold in packaging that includes individual portions of the food; and
(c) any of the individual portions:
(i) are in a solid or semi-solid form (excluding powders); and
(ii) are not designed for individual sale; and
(iii) do not require further preparation before consumption.

The following example of individual portions of formulated supplementary sports food is provided for the reader: 'A formulated supplementary sports food sold in the form of chewables or dissolvable strips that contain caffeine'.

New subsection 2.9.4—12(2) provides that each individual portion of the formulated supplementary sports food referred to in paragraph (b) above must be separately packaged.

According to subsection 1.1.1—10(10) of the Code, if a packaging requirement of the Code applies to the sale of food, the packaging must comply with the requirement.

Consequently, if approved, the effect of new section 2.9.4—12 would be that if formulated supplementary sports food:

- contains more than 200 mg caffeine in total, and
- is sold in packaging that includes individual portions of the food; and

if any of the individual portions:

- are in a solid or semi-solid form (excluding powders);
- are not designed for individual sale; and
- do not require further preparation before consumption,

each individual portion of the formulated supplementary sports food must be separately packaged.

The intent of proposed new section 2.9.4—12 is to ensure that the risk of inadvertent consumption of multiple serves of low volume, caffeinated formulated supplementary sports food is managed.

Schedule 9 – Mandatory advisory statements and declarations

Item [9] proposes to amend Schedule 9 of the Code.

Schedule 9 contains the mandatory advisory statements and declarations required by the Code.

In particular, **item [9]** would amend the table to section S9—2.

The table to section S9—2 sets out mandatory advisory statements for the purposes of subsection 1.2.3—2(1) and paragraph 2.9.5—10(2)(a) of the Code.

Subsection 1.2.3—2(1) requires that for the labelling provisions in Standard 1.2.1—if a food is listed in Column 1 of the table in section S9—2, the corresponding advisory statement in Column 2 of that table is required.

Paragraph 2.9.5—10(2)(a) applies specifically to food for special medical purposes and does

not apply to formulated supplementary sports food.

Item [9] would amend the table to section S9—2 by adding a new entry at the end of the table (entries are ordered numerically by item numbers).

The new entry consists of:

- the number '12' in the column headed *Item*,
- 'A formulated supplementary sports food that contains caffeine' as the food in the Column 1 of the table, and
- 'the food contains caffeine.' as what must be indicated by the advisory statement in Column 2 of the table.

According to subsections 1.1.1—10(8) and 1.1.1—10(9) of the Code respectively:

- if a labelling requirement of the Code applies to the sale of food, the labelling must comply with the requirement; and
- if an information requirement of the Code applies to the sale of food, the information must be provided as required.

Consequently, if approved, the effect of the proposed amendment in **item [9]** would be that where formulated supplementary sports food contains caffeine—an advisory statement indicating that the food contains caffeine must be provided in accordance with Standard 1.2.1 for the food.

The intent of this proposed amendment is to alert consumers to the fact that the formulated supplementary sports food contains caffeine.