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

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385-26

Approval report – Proposal P1056

Caffeine review

Food Standards Australia New Zealand (FSANZ) has prepared and 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.

On 4 March 2025, FSANZ sought submissions on a draft food regulatory measure extending across 6 standards and published an associated report. FSANZ received 23 submissions. On 31 October 2025, FSANZ sought submissions on additional proposed changes via a consultation paper. FSANZ received 25 submissions.

After having regard to the submissions received and the relevant matters as set out in this report, FSANZ approved the draft variations on 10 March 2026. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 24 March 2026.

This report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991*.

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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Supporting documents

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

SD1	Safety Assessment of Caffeine at Approval
SD2	Dietary Intake Assessment
SD3	Social Science Literature Review at Approval
SD4	Assessment of Caffeine and Sports Performance
SD5	Decision Regulation Impact Statement

Executive summary

Introduction

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 identified there is a risk of acute poisoning from inadvertent consumption of concentrated caffeine products. As a result of P1054, the Australia New Zealand Food Standards Code (the Code) was amended 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.

For the reasons stated in the P1054 Amendment of the approved variation, P1056 considered whether additional measures were required in relation to the regulation of caffeine in the Australian and New Zealand food supply to protect public health and safety. Specifically, the proposal examined:

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

Risk assessment

FSANZ conducted a risk assessment which identified safe levels of caffeine intake in the general population and sensitive subpopulations. In summary:

- Caffeine intakes of up to 210 mg caffeine and 400 mg/day (5.7 mg/kg body weight/day) were not associated with adverse effects in non-pregnant adults.
- Caffeine intake in pregnant women above 200 mg of caffeine per day may increase the risk of miscarriage, stillbirth, preterm delivery, low birthweight and small for gestational age infants.
- In children, consumption of up to 3 mg/kg body weight/day[2] caffeine is considered safe based on an extrapolation from adults.

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) were regularly exceeding the safe limit of caffeine intake.

FSANZ's social science assessment found evidence that up to 15% of pregnant women were regularly exceeding the safe limit of caffeine intake. Some other sub-populations also typically consumed more than the safe limit of caffeine (e.g. university students, nurse and midwife shift workers).

A product scan found that caffeine can be present at high concentrations in sports foods, and that some products on the market exceed the safe level for a single intake of caffeine.

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

Data from poison centres in Australia and New Zealand showed that infants and toddlers were over-represented among calls related to acute caffeine intake. Infants and pre-schoolers can be at higher risk than adults of caffeine poisoning due to their lower bodyweights relative to adults.

Risk management

The Code does not currently 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.

These requirements are no longer considered sufficient to manage risks to public health and safety or to effectively regulate the breadth of products that have become available in Australian and New Zealand. The following amendments establish clear requirements in Australia and New Zealand to ensure the continued protection of public health and safety, particularly for sensitive sub-populations, and bring increased certainty to the regulatory requirements in relation to the use of caffeine in the general food supply and in FSSF.

After considering all submissions received, FSANZ approved a draft variation to make the following changes to the Code:

- Prohibit the retail sale of caffeine and guarana extract 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
  - 1% or more of the food for sale if that food is a liquid.
- Expressly permit FSSF to contain up to 200 mg caffeine (in total, from any source), in a one-day quantity (i.e. the amount of FSSF which is to be consumed in one day in accordance with directions specified on the label).
- 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
  - 1% or more for a FSSF in a liquid form.
- Set new labelling requirements for coffee-containing beverages that contain 200 mg or greater caffeine content, namely, new advisory statements and a requirement to declare caffeine in the nutrition information panel (NIP).

The approved draft variation will not impact the sale of foods such as coffee, teas and chocolate, except for some packaged coffee-containing beverages that exceed 200 mg caffeine per serve, which will be subject to new labelling requirements.

Abbreviations and glossary

Term	Description
bw	Body weight
CFS	Call for submissions
Code	Australia New Zealand Food Standards Code
EC	European Commission
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
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 included:

- the addition of caffeine to Formulated Supplementary Sports Foods (FSSF) and other foods in the general food supply
- the extent of the risk posed to sensitive 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 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
(b) prepare a proposal for the further variation of the Code as amended by that variation.

For the reasons stated in the P1054 Amendment report (FSANZ 2020), FSANZ decided to prepare a further proposal (P1056) 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 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
- the extent of the risk posed to sensitive subpopulations and whether and how any such risk should best be managed.

The approved variation prepared under P1054 will remain unchanged and in force unless and until amended or repealed. This ensures ongoing protection of consumers from pure and highly concentrated caffeine products pending the outcome of P1056.

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 was assessed under the Major Procedure as set out in the FSANZ Act, which requires 2 rounds of statutory public consultation. These were completed in December-February 2022-23 and March-April 2025 (FSANZ 2022, FSANZ 2025). This approval report provides a record of all consultation undertaken and subsequent decisions. Summary tables of the issues raised in submissions to the 2nd call for submissions (CFS) and our responses to those issues are provided in Appendix 1.

An additional consultation paper including revisions to the proposed draft variation was released in October 2025 (FSANZ 2025b). Summary tables of the issues raised in submissions to the consultation paper and our responses to those issues are provided in Appendix 2.

Submissions received in response to the 2nd CFS and the consultation paper informed FSANZ's decision on whether to approve, amend or reject the proposed draft variation. More detail on specific issues raised by submitters is in section 3.1 of this report.

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 current Code in-force

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 as 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)[3] 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 food additive 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

[3] 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.

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 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'[4]—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)).

In general, 'advisory statements' are required by the Code for certain foods or ingredients that may cause health risks for some consumers. In contrast, a 'warning statement' is typically required when the health risk is very serious (potentially fatal), and a consumer is unlikely to be aware of this risk. The exact wording and font size of a warning statement is prescribed whereas the wording and font size of an advisory statement is not, although the intended advisory statement must still be accurately and legibly conveyed.

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
- 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 those products pose to public health and safety. In Australia, the Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, Disability and Ageing and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.

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 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.[5]

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

1.4.3 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:

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[4] 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.

[5] Regulation of sport supplements in Australia: information for importers and sellers | Therapeutic Goods Administration (TGA)

- 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[6] (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 less than 5% of 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[7].

Schedule 6[8] 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.

1.4.4 *The New Zealand (Supplemented Food) Standard 2016*

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.[9] 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*[10] 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

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[6] Federal Register of Legislation - Therapeutic Goods (Poisons Standard—June 2024) Instrument 2024
[7] 2.1 Caffeine | Therapeutic Goods Administration (TGA)
[8] Understanding storage requirements for Schedule 6 and Schedule 7 chemicals in retail settings | Therapeutic Goods Administration (TGA)
[9] Importing food from New Zealand - DAFF (agriculture.gov.au)
[10] *New Zealand Supplemented Food Standard 2016*

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.

Advice from New Zealand Food Safety (Table D, 2nd CFS (FSANZ 2025) is that paragraph 1.1.1—10(5)(g) of the Code applies to supplemented foods in New Zealand and that NZFS are reviewing the implications of regulatory measures proposed by this Proposal for the caffeine related provisions in the *New Zealand Food (Supplemented Food) Standard 2016.*

The operation of the *New Zealand Food (Supplemented Food) Standard 2016* and the TTMRA are outside of FSANZ's remit and out of scope for P1056.

1.4.5 Regulation of caffeine internationally

FSANZ prepared a summary of the regulation of caffeine in the USA, European Union and Canada at the time of writing (2019), under P1054 (Appendix A – Final Consideration Report (FSANZ 2019)) and provided some additional information in section 1.4.4 of the 2nd CFS in early 2025 (FSANZ 2025).

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.[11] 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 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[12]. 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).

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).

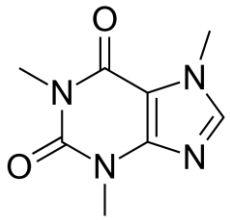
FSANZ notes a further update from Canada (November 2025), whereby the use of caffeine as a supplemental ingredient in foods listed in item 6 of the List of Permitted Supplemented Food Categories is authorised and all solid supplemented foods with high caffeine content must be labelled to indicate that another source of caffeine should not be consumed on the same day[13].

[13] Modification to the List of Permitted Supplemental Ingredients to extend the use of caffeine - Canada.ca

1.5 Chemical characterisation of caffeine

The chemical and physical properties of caffeine are summarised in Table 1. 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

1.6 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 synthesised.

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

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. Unapproved novel foods are not permitted for retail sale or as an ingredient or component in a food for retail sale and therefore are not an authorised source of caffeine.

1.7 Decision

For the reasons outlined in this report, FSANZ has approved an amended version of the proposed draft variation in the second CFS released in March 2025.

The approved draft variation will amend the Code to:

- prohibit the retail sale of caffeine and guarana extract 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
  - 1% or more of the food for sale if that food is a liquid
- expressly permit FSSF to contain up to 200 mg caffeine (in total, from any source), in a one-day quantity (i.e. the amount of FSSF which is to be consumed in one day in accordance with directions specified on the label).
- 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
  - 1% or more for a FSSF in a liquid form
- set new labelling requirements for coffee-containing beverages that contain 200 mg or greater caffeine content.

The draft variation proposed in the 2nd CFS was amended following consideration of submissions in response to that CFS and the consultation paper released in October 2025 as follows:

- to clarify that for the purposes of the proposed prohibition on the retail sale of ‘caffeine’ as a food, ‘caffeine’ means 1,3,7-trimethylxanthine, that is, pure caffeine, and to add a prohibition on the retail sale of ‘guarana extract’, as defined
- to make clear that the proposed prohibition on the retail sale of a food that contained caffeine as an ingredient or component applied to ‘caffeine from any source’ and to add an example
- amendment to Standard 1.5.1 to make clear that a food for retail sale must not consist of, or have as an ingredient or component, caffeine from a novel food unless that novel food is listed as a permitted novel food and any conditions of use are complied with
- to add the following to section 1.1.1—10:
  - examples clarifying how subsection 1.1.1—10(7) (relating to a substance in a food for sale by natural occurrence) applies for the purposes of the prohibition on a food for retail sale containing caffeine
  - subsection 1.1.1—10(7A) which will state that subsection 1.1.1—10(7) does not apply to caffeine present in a food for sale, or in an ingredient of a food for sale, as a result of the addition of guarana extract
- to include new labelling requirements for highly caffeinated packaged beverages containing coffee; namely, new advisory statements and a requirement to declare caffeine in the nutrition information panel
- to include an exemption from individual packaging requirements for certain FSSF, if the FSSF contains caffeine only from cocoa, chocolate, decaffeinated coffee and/or decaffeinated tea (including instant versions)
- to clarify that the concentration limits for FSSF in powder and liquid form apply to caffeine from any source
- to clarify requirements relating to the individual packaging requirement to FSSF
- to include an exemption for FSSF containing caffeine from the new caffeine-related labelling requirements if the caffeine is present only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee (including instant versions)
- to add a requirement for an advisory statement to the effect the food contains caffeine on certain individual portions of FSSF as well as on the outer package of those FSSF

- minor editorial amendments including for further clarity.

The above amendments are explained in section 2.3 of this report.

The approved draft variations are at Attachment A.

The variations take effect on gazettal with a 2-year transition period.

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

The draft variations on which submissions were sought at the 2nd CFS and the consultation paper are at Attachment C and D respectively.

The Decision Regulation Impact Statement (DRIS) is at Attachment E.

2 Summary of the findings

2.1 Summary of issues raised in submissions

2.1.1 1st and 2nd CFS

The 1st CFS, released on 19 December 2022 for a period of 8 weeks, sought feedback on FSANZ's assessment and preliminary conclusion about whether to prepare a variation to the Code. It also included consideration of 3 risk management options. The preferred option was Option 3 which proposed:

- an express prohibition on the addition of caffeine to 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.

After consideration of each submission, FSANZ prepared a proposed draft variation. A 2nd CFS was released for a 6-week consultation period from 4 March to 15 April 2025 to seek feedback on the proposed draft variation and the assessment and regulatory approach on which it was based. FSANZ received 23 submissions to the 2nd CFS (9 government, 9 industry, 5 public health/consumer).

FSANZ has carefully analysed the comments in each submission. Submitter comments and FSANZ responses, including where a change was made to the proposed draft variation, are captured in tables in Appendix 1. The tables summarise submitter comments to the 2nd CFS and FSANZ considerations and decisions.

Submissions are publicly available on FSANZ's website.

2.1.2 Consultation paper

After consideration of submissions to the 2nd CFS, FSANZ prepared amendments to the draft variation proposed in the 2nd CFS. From 31 October to 12 December 2025, FSANZ sought submissions on those proposed amendments via a consultation paper (FSANZ 2025). FSANZ received 25 submissions to the consultation paper (5 government, 14 industry, 4 public health/consumer and 2 confidential).

Submitter comments and FSANZ responses, including where a change was made to the proposed draft variation, are captured in tables in Appendix 2. The tables summarise

submitter comments to the consultation paper and FSANZ considerations and decisions.

Non-confidential submissions are publicly available on FSANZ's website.

2.1.3 WTO consultation

In September 2024 FSANZ made notifications to the World Trade Organization (WTO) for this proposal in accordance with the WTO Agreement on Technical Barriers to Trade (TBT). No comments were received from member countries.

Further notifications were made in November 2025 to the WTO for this proposal in accordance with the WTO Agreement on TBT and on Sanitary and Phytosanitary Measures (SPS).

A comment was received in response to the NZ SPS notification from one member country. The comment received is addressed in Table 1 of Appendix 3.

2.2 Risk Assessment

FSANZ has undertaken comprehensive assessments of all relevant issues, including a hazard assessment, dietary intake assessment, a social science literature review and an assessment of caffeine and sports performance. All were published as supporting documents to the 1st CFS and are also appended to this approval report (Supporting Documents 1 through to 4).

2.2.1 Hazard assessment

The key conclusions of the assessment as 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[14] 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 can be at higher 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 intake.

[14] 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.

2.2.2 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.

2.2.3 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 in addition to the broader population.

The findings complement and extend the findings of FSANZ's dietary intake assessment, particularly for the subpopulation of pregnant women, which could not 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 caffeine 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 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.

2.2.4 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 have changed since the completion of the National Nutrition Surveys used in the dietary intake assessment. In the first release of data from the 2023 National Nutrition and Physical Activity Survey, average daily caffeine intake in the adult population increased from 158 mg in 2011-12 to 186 mg in 2023. For children aged 2-17 years, average daily caffeine intake increased from 17 mg in 2011-12 to 22 mg in 2023. (Australian Bureau of Statistics, 2025). These Day 1 intakes are within normal daily variation.

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.

2.3 Risk Management

The following sections outline the risk management approaches in the 1st CFS, 2nd CFS and the consultation paper, as appropriate for each measure or matter.

2.3.1 Express prohibition on the retail sale of caffeine as a food

2.3.1.1 1st CFS

For the reasons stated in the 1st CFS (FSANZ 2022), FSANZ proposed to expressly prohibit the addition of caffeine to foods, apart from the express permissions in cola-type drinks and FCBs and as proposed for FSSF. This meant that the P1054 variation would no longer be required under the preferred option and would therefore be omitted from the Code (see section 2.3.4 below regarding removal of the P1054 variation).

Submitter feedback to the 1st CFS

The proposed approach for an express prohibition 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).

2.3.1.2 2nd CFS

In the 2nd CFS, a proposed draft variation was prepared where FSANZ included an express prohibition on the retail sale of caffeine as a food, by listing 'caffeine' in paragraph 1.1.1—10(5)(g) and repealing the current paragraph (the P1054 variation). For the reasons set out in the 2nd CFS, FSANZ prepared and sought submissions on a proposed draft variation to prohibit the retail sale of caffeine as a food unless expressly permitted by the Code. This prohibition would replace the P1054 prohibition. In the proposed draft variation, 'caffeine' was not defined.

Submitter feedback to the 2nd CFS

Some submissions received in response to the 2nd CFS (see Table 2, Appendix 2) raised issues in relation to the above approach, particularly the retail sale of highly concentrated caffeinated products arising from the proposed removal of the restrictions imposed by paragraph 1.1.1—10(5)(g) which applied to any food for retail sale (see section 2.3.4 below).

Guarana extract was identified as the plant extract of most concern to submitters. It was noted that guarana extract can be produced to contain high levels of caffeine (e.g. 22%) but the content can be even higher.

2.3.1.3 Consultation paper

After considering submitter comments, for the reasons set out in the consultation paper (section 2.2.1.1, FSANZ 2025b), FSANZ proposed instead to prohibit the retail sale of 'prescribed caffeine product' unless expressly permitted by the Code. A prescribed caffeine product was defined to mean 1,3,7-trimethylxanthine and guarana extract.

Submitter feedback to the consultation paper

Submitter comments to the consultation paper and FSANZ responses, including where a change was made to the draft variation, are captured in Table 2, Appendix 2 of this report.

Submitters generally supported the prohibition of the retail sale of caffeine and of guarana extract as foods for retail sale. Some submitters sought a definition of guarana extract.

2.3.1.4 Discussion

After considering submitter comments, FSANZ decided to define what constitutes 'guarana extract' for the purposes of the definition of 'prescribed caffeine product' and the above-mentioned prohibition.

The definition will in effect set a compositional limit for caffeine in guarana extract as a food for retail sale. That is, the prohibition on guarana extract as a 'prescribed caffeine product' and as a food for retail sale would apply only to guarana extract containing caffeine at a concentration of: 5% or more if the product is in a solid or semi-solid form; or 1% or more if the product is in a liquid.

These limits align with the P1054 variation.

The above change will not impact the retail sale of guarana extract as the retail sale of products containing caffeine at these concentration limits is already prohibited, unless expressly permitted in the Code.

In developing the definition of guarana extract and in setting these caffeine limits, FSANZ also had regard to the following:

- If guarana seeds are dried and produced in powdered form (i.e. there is no extraction process involved), the caffeine concentration is around 3% - 5%.
- Guarana extract is produced from the guarana (*Paullinia cupana*) seed, resulting in a product where the concentration of caffeine exceeds that which occurs in the seed by natural occurrence.
- Guarana extracts vary in composition (including caffeine content), depending on the extraction ratio and method of extraction. There is evidence that some currently available guarana extracts are highly concentrated sources of caffeine (e.g. 22% caffeine). These extracts are of acute safety concern.
- Caffeine concentrations in guarana can exceed those found in traditional caffeinated foods such as coffee, tea, cocoa and chocolate.

Additionally, the definition of prescribed caffeine product has been amended to clarify that for the purposes of the prohibition, 'caffeine' means 1,3,7-trimethylxanthine, that is, pure caffeine.

2.3.1.5 Decision

The approved draft variation will prohibit the retail sale of a 'prescribed caffeine product' unless that sale is expressly permitted by the Code; and define a 'prescribed caffeine product' to mean caffeine (i.e., 1,3,7-trimethylxanthine) and guarana extract.

New subsection 1.1.2—3(2) will define the term 'guarana extract' to mean a product that:

(a) is produced from guarana seeds by use of an extraction process; and
(b) contains caffeine at a concentration of:
    (i) 5% or more – if the product is in a solid or semi-solid form;
    (ii) 1% or more if the product is in a liquid.

2.3.2 Prohibition of caffeine as an ingredient or component of a food for sale

2.3.2.1 2nd CFS

For the reasons set out in the 2nd CFS, the proposed draft variation issued with that CFS included a prohibition on the retail sale of a food that contained caffeine as an ingredient or component. (See that variation's proposed amendment to paragraph 1.1.1—10(6)(k).)

Submitter feedback to the 2nd CFS

Some submitters questioned the meaning of caffeine and whether the prohibition would apply to sources of caffeine that are plant extracts (such as guarana extract).

Detailed submitter comments and FSANZ responses to this issue are captured in Table 2, Appendix 1 of this report.

2.3.2.2 Consultation paper

For the reasons set out in the consultation paper, FSANZ proposed to amend the draft variation proposed in the 2nd CFS to make clear that the above prohibition applied to 'caffeine from any source'.

The reference to 'any source' would capture caffeine present in the food for retail sale as a result of the addition of guarana extract.

It was proposed to include an example in the Code to make this clear. The proposed example stated: *A food for retail sale that contains caffeine as an ingredient or component as a result of the addition of pure caffeine or of guarana extract.*

The prohibition would not apply to a food for retail sale that the Code expressly permits to contain caffeine as an ingredient or component.

Subsection 1.1.1—10(7) of the Code would also provide that the prohibition does not apply to caffeine that is in a food for sale, or in an ingredient of a food for sale, by natural occurrence (see section 2.3.3).

For the reasons set out in the consultation paper, FSANZ also proposed to change the draft variation to include an amendment to Standard 1.5.1 of the Code. That amendment would make clear that a food for retail sale must not consist of, or have as an ingredient or component, caffeine from a novel food unless that novel food is listed in the Code as a permitted novel food, and any conditions of use prescribed by the Code for that novel food are complied with. (See proposed subsection 1.5.1—3(3) in Attachment D.)

Submitter feedback to the consultation paper

Submitter feedback from the consultation paper was mixed.

Some, while supportive of the overall intent of the provision, sought further clarity in the proposed revisions on plant extracts other than guarana.

Some supported the prohibition on guarana extract as an ingredient in a food for retail sale and some, whilst supporting the intent, sought clarification on the definition of guarana extract and/or its use as an ingredient or flavouring or when minimal amounts of caffeine are added.

Some submitters opposed the prohibition on guarana extract outright citing, for example,

over prescriptiveness, inhibition of innovation, and cost to industry disproportionate to the risk. Others requested an exemption for alcoholic beverages from the prohibition on guarana extract citing a lack of evidence of risk, in particular to sensitive populations.

Submitter comments to the consultation paper and FSANZ responses, including where a change was made to the draft variation, are captured in Table 2, Appendix 2 of this report.

2.3.2.3 Discussion

FSANZ considers none of the issues raised by submitters to the consultation paper require a change in FSANZ's overall position on the addition of caffeine to food as an ingredient or component.

FSANZ's assessment is that the use of caffeine-rich extracts would be appropriately regulated by measures such as:

- The above-mentioned prohibition on the retail sale of foods containing caffeine as an ingredient or component.
- The existing Code restrictions on novel foods being a food for retail sale or an ingredient or component of a food for retail sale. Some caffeine-rich plant extracts may be novel foods and therefore unable to be sold at retail sale or be present in a food for retail sale as an ingredient or component unless expressly permitted by the Code.
- The clarification on guarana extract (see section 2.3.1) which addresses the safety risks associated with the sale and addition to food of guarana extract when it is a concentrated source of caffeine.

The following is also noted:

- Use of any plant extract (including guarana, as per the proposed definition) that is a source of caffeine will be subject to the prohibition on food for retail sale containing caffeine as an ingredient or component unless expressly permitted.
- Extracts that are novel foods for the purposes of the Code would require premarket assessment and an express permission in the Code before they could be present in a food for retail sale as an ingredient or component.

FSANZ's safety assessment identified several risks to the population from caffeine in food (SD1, FSANZ 2022 and section 2.1.4, 2nd CFS (FSANZ 2025)) that warranted a regulatory approach to the addition of caffeine as an ingredient in food (including alcoholic beverages). The proposed regulatory approach at the 2nd CFS 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). FSANZ has conducted a full Decision Regulatory Impact Statement (DRIS), which concluded that direct and indirect benefits to the community, government and industry would arise from amending the Code as proposed by P1056 and are expected to outweigh the costs and return a net benefit (see section 4.1.1).

FSANZ considers the current permissions to add caffeine to cola-type drinks and FCBs and the new permission for FSSFs (section 2.3.6), 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.

For clarity, FSANZ decided to amend the example provided under paragraph 1.1.1—

10(6)(k). The amendment clarifies that 'pure caffeine' is caffeine (1,3,7-trimethylxanthine) and that the addition of caffeine via plant extracts is not limited to guarana extract.

The new definition for guarana extract (subsection 1.1.2—3(2)) (see section 2.3.1 above) applies to 'guarana extract' in the example under paragraph 1.1.1—10(6)(k) and to 'guarana extract' in paragraph 1.1.1—10(7A). It does not apply to the references to 'guarana' and 'extracts of guarana' in column 1 in the Table to S9—2 as these do not refer specifically to 'guarana extract'. The requirement for advisory statements indicating that the food contains caffeine for foods that contain guarana or extracts of guarana will therefore continue to apply as it currently does.

Regarding the use of guarana or guarana extract in FCBs and FSSF, caffeine is permitted 'from any source' (subsection 2.6.4—3(a) and the new paragraph 2.9.4—3(2)(b)). In other words, for manufacturers of FCBs and FSSF that use guarana or guarana extract as a source of caffeine in those products, the amendments do not change their ability to do so, subject to limits on the amount of caffeine permitted, in the respective Standards.

See also FSANZ's responses to submissions in Table 2, Appendix 2 of this report.

2.3.2.4 Decision

The approved draft variation will include new paragraph 1.1.1—10(6)(k) which sets out that unless expressly permitted by the Code, food for retail sale must not have as an ingredient or a component, caffeine from any source.

Example A food for retail sale that contains caffeine as an ingredient or component as a result of the addition of caffeine (1,3,7-trimethylxanthine) or of a plant extract including but not limited to guarana extract.

The approved draft variation will also include new subsection 1.5.1—3(3) to provide that a food for retail sale must not have as an ingredient or component, caffeine from a novel food unless:

(a) the novel food is listed in the table to section S25—2; and

(b) any conditions of use specified in the corresponding row of that table are complied with.

2.3.3 Caffeine in food by natural occurrence

As mentioned above, FSANZ proposed to amend subsection 1.1.1—10(6) to prohibit a food for retail sale containing, as an ingredient or component, caffeine from any source unless expressly permitted by the Code.

The prohibitions imposed by subsection 1.1.1—10(6) apply subject to the exemption provided by subsection 1.1.1—10(7). That subsection provides that subsection 1.1.1—10(6) does not apply to a substance that is in a food for sale, or in an ingredient of a food for sale, by natural occurrence.

The above would mean the proposed prohibition of a food for retail sale containing, as an ingredient or component, caffeine from any source would not apply to caffeine in a food for retail sale, or in an ingredient of a food for retail sale, by natural occurrence.

2.3.3.1 2nd CFS

FSANZ proposed in the 2nd CFS a prohibition on the retail sale of a food that contained

caffeine as an ingredient or component (see above). No amendment to subsection 1.1.1—10(7) was proposed.

Submitter feedback to the 2nd CFS

There was some stakeholder uncertainty about the operation of subsection 1.1.1—10(7) including requests for clarity regarding caffeine by natural occurrence. Submitter comments and FSANZ responses to this issue are captured in Table 2, Appendix 1 of this report.

Where a change was made to the draft variation, relevant submitter comments were captured and responded to in section 2.2.2 and Table 3 of the consultation paper (FSANZ 2025b).

2.3.3.2 Consultation paper

For the reasons set out in the consultation paper (section 2.2.2, FSANZ 2025b)), FSANZ proposed to:

- amend section 1.1.1—10 by adding an example clarifying how subsection 1.1.1—10(7) applied for the purposes of the proposed prohibition on a food for retail sale containing caffeine; and
- add new subsection 1.1.1—10(7A).

The proposed example explained caffeine present in a food for sale, or in an ingredient of a food for sale, only as a result of the addition of cocoa, chocolate, coffee or tea, is caffeine that is in the food for sale or the ingredient by natural occurrence. The caffeine occurs naturally in the cocoa, chocolate, coffee or tea. Subsection 1.1.1—10(7) will therefore apply to and exempt that caffeine from the prohibition imposed by new paragraph 1.1.1—10(6)(k).

New subsection 1.1.1—10(7A) would provide that subsection 1.1.1—10(7) does not apply to guarana extract. That is, caffeine from guarana extract in a food for retail sale would be subject to the prohibition set by new paragraph 1.1.1—10(6)(k).

The consultation paper also explained that subsection 1.1.1—10(7) of the Code cannot itself permit the retail sale of a caffeine-containing plant that is an unapproved novel food.

2.3.3.3 Submitter feedback to the consultation paper

Submitter feedback from the consultation paper was generally supportive of clearer regulation of naturally occurring caffeine, however submitter feedback on the new subsection 1.1.1—10(7A) was divided.

Some raised that the proposed example could be interpreted as an exhaustive list of caffeine-containing plants that were considered ‘by natural occurrence’ and suggested deleting the word ‘only’ for clarity. Some noted other plant extracts that were left out of the example, with some suggesting adding other plant extracts to the example to better demonstrate what constitutes ‘unnaturally elevated’ caffeine levels.

Some supported the exception for guarana by natural occurrence on the basis of public health and safety, but others considered the exception should not apply to guarana extract on the basis that it was considered safe and has a history of use in the food supply. Some suggested that excluding guarana extract, and not other plant extracts, would cause confusion and is not risk proportionate.

Submitter comments to the consultation paper and FSANZ responses, including where a

change was made to the draft variation, are captured in Table 2, Appendix 2 of this report.

2.3.3.4 Discussion

After considering submissions, FSANZ's position on subsection 1.1.1—10(7) and the proposed amendments, as outlined in the sections above, has not changed. FSANZ has, however, made the following changes when approving the proposed draft variation:

- The word 'only' was removed from the example to avoid it being read as being an exhaustive list of caffeine sources and the example was separated into two examples for clarity.
- Subsection 1.1.1—10(7A) has been reworded to better reflect how the relevant provisions operate. That is, subsection 1.1.1—10(7A) will state that subsection 1.1.1—10(7) does not apply to caffeine present in a food for sale, or in an ingredient of a food for sale, as a result of the addition of guarana extract.
- The new definition in subsection 1.1.2—3(2) of guarana extract will also apply to the references to guarana extract in subsection 1.1.1—10(7A).

See sections 2.3.1 and 2.3.2 above for FSANZ's rationale on the prohibition on guarana extract.

2.3.3.5 Decision

The approved draft variation will amend subsection 1.1.1—10(7), to include examples of what is and is not the presence of caffeine by natural occurrence, as follows:

- Caffeine present in a food for sale, or in an ingredient of a food for sale, as a result of the addition of cocoa, chocolate, coffee or tea; is caffeine that is in the food for sale or the ingredient by natural occurrence. The caffeine occurs naturally in the cocoa, chocolate, coffee or tea.
- Caffeine present in a food for sale, or in an ingredient of a food for sale, as a result of the addition of caffeine (1,3,7-trimethylxanthine) is not caffeine in the food for sale or the ingredient by natural occurrence.

The approved draft variation will also insert new subsection 1.1.1—10(7A), stating that subsection (7) does not apply to caffeine present in a food for sale, or in an ingredient of a food for sale, as a result of the addition of guarana extract.

2.3.4 Removal of the P1054 variation

2.3.4.1 1st CFS

In the 1st CFS FSANZ proposed the removal of paragraph 1.1.1—10(5)(g) of the Code. That paragraph was added to the Code under P1054 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
- 1% or more of the food for sale if that food is a liquid.

2.3.4.2 2nd CFS

In the 2nd CFS, FSANZ maintained its approach proposed in the 1st CFS, for the following reasons:

- 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 would mean that the 1% and 5% restrictions imposed by paragraph 1.1.1—10(5)(g) of the Code were no longer required.

Submitter feedback to the 2nd CFS

Submitters' views were mixed regarding the removal of the P1054 amendments. Some requested greater clarity on the regulation of highly concentrated caffeine-containing plant extracts whereas others considered the proposed removal would stifle innovation.

Submitter comments to the 2nd CFS and FSANZ responses are captured in Table 2, Appendix 1 of this report.

2.3.4.3 Consultation paper

FSANZ did not specifically request feedback on the removal of the 1% and 5% concentration limits in the consultation paper, however some of the proposed revisions to Standard 1.1.1 in the draft variation proposed in the consultation paper related to submitter feedback from the 2nd CFS. See Tables 2 and 3 of the consultation paper for relevant submitter comments and FSANZ responses to the issue. (FSANZ 2025b).

2.3.4.4 Discussion

The approved draft variation will result in the following:

- The sale of caffeine and of guarana extract as a food will be prohibited unless expressly permitted by the Code. See section 2.3.1 above.
- The addition of caffeine to food (or as a source of caffeine, such as guarana extract) will be prohibited unless expressly permitted by the Code. See section 2.3.2 above
- FSSF containing caffeine from any source at a concentration of 5% or more if in a powdered form or of 1% or more if in a liquid form will be prohibited. See section 2.3.7 below.
- Beverages high in caffeine will be subject to new labelling requirements. See section 2.3.5 below.

The above regulate the highly concentrated caffeinated substances considered to pose a risk under P1054.

No evidence has been identified to warrant a change in FSANZ's position that the above measures meant the P1054 amendment is no longer required.

2.3.4.5 Decision

For the reasons listed in this report, FSANZ approved a draft variation to the Code that will, among other things, repeal current paragraph 1.1.1—10(5)(g) of the Code.

2.3.5 High caffeine coffee beverages

2.3.5.1 1st and 2nd CFS

FSANZ did not propose any amendments to the Code in the 1st or 2nd CFS for general food products with added ingredients or components containing caffeine by natural occurrence, such as coffee, tea or chocolate. Due to the exemption provided by subsection 1.1.1—10(7), the proposed prohibition on the retail sale of caffeine as an ingredient or component of a food (paragraph 1.1.1— 10(6)(k)) would not apply to caffeine that is in a food for retail sale by natural occurrence.

Submissions received in response to the 2nd CFS raised concerns about the risks to consumers of beverages containing coffee that are high in caffeine.

2.3.5.2 Consultation paper

FSANZ considered the issue raised by submitters and subsequently proposed revisions to the draft variation released with the consultation paper for public comment in October 2025 (FSANZ, 2025b). The issues raised are summarised and responded to in section 2.2.3 and Table 4 of the consultation paper (FSANZ 2025b).

For the reasons set out in section 2.2.3.1 of the consultation paper, FSANZ proposed new labelling requirements for highly caffeinated packaged beverages containing coffee; namely, new advisory statements and a requirement to declare caffeine in the NIP. These proposed requirements would apply to:

- packaged beverages containing coffee that contain no less than 200 mg caffeine per serving, and
- where those beverages are subject to the requirement to be labelled with a NIP in accordance with section 1.2.8—5 of the Code.

The proposed advisory statements were to the effect that the beverage is high in caffeine and that it is not suitable for children under 15 years of age or pregnant or breastfeeding women.

The proposed labelling would not be required for coffee beverages that are exempt from the requirement to bear a label (under section 1.2.1—6 of the Code), for example, if they are made and packaged from the premises from which they are sold, or packaged in the presence of the purchaser, for example, a cup of coffee purchased from a café. The proposed labelling would also not be required for coffee beans (including ground) and instant coffee (with no water added). These are not a beverage and are also exempt from the requirement to have a NIP (unless a claim requiring nutrition information is made in relation to the food) (subparagraph 1.2.8—5(2)(a)(v) of the Code).

Packaged beverages containing coffee that would be subject to the proposed labelling would be required to include the advisory statement on individual portion packs[15] in addition to the outer layer of packaging. This approach would ensure the information is available to consumers in the event the individual portion pack is separated from the outer packaging.

[15] As described in subsection 1.2.1—6(3), individual portion packs are in food for sale sold in packaging that includes individual packages for servings that are intended to be used separately but which (a) are not designed for individual sale; and (b) have a surface area of 30 cm^2 or greater.

Submitter feedback to the consultation paper

Submitters supported the approach proposed in the consultation paper. Some submitters suggested a warning statement should be required instead of an advisory statement, and that serving sizes should be standardised. Submitter comments and FSANZ responses to the consultation paper are captured in Table 2, Appendix 2 of this report.

2.3.5.3 Discussion

FSANZ considers there were no issues raised by submitters that require amendments to the proposed approach in the consultation paper. For the reasons outlined in section 2.3.1.1 of the consultation paper, the approach proposed in that paper has been maintained.

This approach is based on FSANZ's risk assessment (FSANZ 2025, SD1, 2 and 3), current industry practice and stakeholder comments. FSANZ considers the new labelling measures are a risk-proportionate approach to mitigate the risk of inadvertent overconsumption of caffeine via high caffeine coffee beverages, particularly for sensitive subpopulations.

A warning statement has not been required because FSANZ considered it was not commensurate with the risk posed by these products. The wording of the advisory statements is similar to the advisory statements required for FCBs in subsection 2.6.4—5(3) of the Code.

FSANZ has not standardised serving sizes, as suggested by some submitters, because this would not limit the amount of caffeine in a product. A compositional limit would achieve that, however a compositional limit on caffeine in coffee-containing beverages has not been set for the reasons outlined in section 2.2.3.1 of the consultation paper. That is, it was not proportionate with the level of risk posed and would be challenging to enforce without labelling of the amount of caffeine present on all coffee beverages, regardless of the amount of caffeine they contain. However, FSANZ considers it is appropriate for consumers to be informed of the caffeine content of higher caffeine coffee products to assist them in managing their caffeine intake.

Minor editorial amendments have been made to section 2.10.4—3A in the draft variation proposed in the consultation paper in response to feedback from submitters to correct a heading and to clarify that the average quantity of caffeine that must be declared is caffeine 'from any source'.

2.3.5.4 Decision

The approved draft variation will set the following labelling requirements for high caffeine coffee beverages:

(a) declaration in the NIP of the average quantity of caffeine, expressed in milligrams, in a serving of the food and in a unit quantity of the food

(b) advisory statements to the effect that the food is high in caffeine and not suitable for children under 15 years of age, or pregnant or breastfeeding women.

See paragraph 1.2.1—8(1)(zb) and section 2.10.4—3A of Standard 2.10.4 (Miscellaneous standards for other foods) of the draft variation.

A high caffeine coffee beverage is defined as a packaged beverage with a NIP that is a food for retail sale, contains coffee and no less than 200 mg caffeine per serving. The definition states that formulated caffeinated beverages and formulated supplementary sports foods are

not high caffeine coffee beverages. See subsection 1.1.2—3(2) of the draft variation.

2.3.6 200 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.

2.3.6.1 1st CFS

In the 1st CFS FSANZ proposed to permit a maximum of 200 mg of caffeine in a one-day quantity in FSSF in conjunction with labelling requirements. The reasons for this are outlined in section 3.2.1.6 of the 1st CFS (FSANZ 2022).

Submitter feedback to the 1st CFS

Submitters generally supported the proposal to permit up to a maximum of 200 mg of caffeine in a one-day quantity in FSSF. Submitter feedback to the 1st CFS is provided in section 2.2.3.1 of the 2nd CFS.

2.3.6.2 2nd CFS

FSANZ proposed in the 2nd CFS 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 2.2.3 of the 2nd CFS) (FSANZ 2025).

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 per 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.

Submitter feedback to the 2nd CFS

Most submitters to the 2nd CFS supported the proposed approach 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.

Some submitters that were supportive of the 200 mg maximum one-day quantity provided additional comments. These comments are included in Table 2, Appendix 1 to this report.

Some submitters did not support the 200 mg one-day quantity, and these comments are also included in Table 2, Appendix 1 to this report.

2.3.6.3 Discussion

Section 2.2.3.2 of the 2nd CFS outlines the evidence and rationale for amending the Code to include an express permission for FSSF to contain a maximum of 200 mg of caffeine in a one-day quantity.

Submitter comments have been responded to in Table 2, Appendix 1 to this report. These comments did not result in changes to the drafting relating to the express permission for FSSF to contain a maximum of 200 mg of caffeine in a one-day quantity.

2.3.6.4 Decision

For the reasons stated in this report, FSANZ reaffirms its position at the 2nd CFS to permit

FSSF to contain caffeine up to a maximum of 200 mg per one-day quantity. This requirement is included in section 2.9.4—3(2)(b) of the approved draft variation.

2.3.7 Additional restrictions for the addition of caffeine to FSSF

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

Section 3.2.2 of the 1st CFS and section 2.2.2 of the 2nd CFS proposed the removal of paragraph 1.1.1—10(5)(g) of the Code. Proposal 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
- 1% or more of the food for sale if that food is a liquid.

2.3.7.1 1st CFS

At the 1st CFS FSANZ did not propose any additional risk management measures for the addition of caffeine to FSSF.

2.3.7.2 2nd CFS

At the 2nd CFS (in section 2.2.4) FSANZ considered feedback received from submitters to the 1st CFS and revised its approach to propose the following:

- caffeine must not be present in a FSSF in a powdered form at a concentration of 5% or more
- caffeine must not be present in a FSSF in a liquid form at a concentration of 1% or more
- individual wrapping of all solid and semi-solid individual portions 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 of caffeine.

Submitter feedback to the 2nd CFS

Caffeine concentration limits for FSSF in powder and liquid form

Most submitters to the 2nd CFS supported the proposal that:

- caffeine must not be present in a FSSF in a powdered form at a concentration of 5% or more
- caffeine must not be present in a FSSF in a liquid form at a concentration of 1% or more (subsection 2.9.4—3(3)).

Two submitters commented it was not clear the concentration limits for powder and liquid refer to caffeine from any source and suggested that subsection 2.9.4—3(3) specifically refer to caffeine from any source.

Other comments received on the concentration limits for FSSF are included in Table 2, Appendix 1 to this report.

Packaging requirements for solid and semi-solid FSSF in a multi-pack

Submitters to the 2nd CFS generally supported the proposal to require individual wrapping of all solid and semi-solid pieces within a multi-pack of caffeine-containing FSSF, when the

pieces require no further preparation, and the multi-pack contains more than a total of 200 mg of caffeine.

Submitters made the following comments that resulted in changes to the drafting.

One submitter suggested rewording ‘small separate portions’ to instead focus on FSSF sold in a multi-serve pack, suggesting the word small is unnecessary. The same submitter also sought clarification and recommended a revision to the drafting to indicate that each individual portion is intended to be consumed in one setting or within a day and recommended introducing a maximum caffeine limit of 200 mg per portion.

Another submitter suggested that the example in proposed section 2.9.4—12 should not be used to provide an indication of whether caffeine-containing dissolvable strips should be regulated as food.

Another submitter sought clarification on whether the wording ‘more than 200 mg of caffeine in total’ refers to an individual portion or the entire multi-pack.

Other submitter comments on this proposed amendment are included in Table 2, Appendix 1 to this report.

2.3.7.3 Discussion

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), FSANZ noted that certain FSSF 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 caffeine-containing products are FSSF in powder and liquid form and solid and semi-solid (excluding powders) in a multi-pack.

Caffeine concentration limits for FSSF in powder or liquid form

Section 2.2.4 of the 2nd CFS outlines the evidence and rationale for retaining the less than 5% and 1% caffeine concentration limits in FSSF in powder and liquid form respectively.

The intent is that all limits for caffeine in FSSF, including the concentration limits for powders and liquids, apply to the caffeine added as the chemically synthesised form, together with any caffeine added from a plant source. Subsection 2.9.4—3(3), which relates to concentration limits, is subject to and should be read in conjunction with paragraph 2.9.4—3(2)(c), which relates to the 200 mg caffeine permission from any source in FSSF. The explanatory statement also makes it clear that subsection 2.9.4—3(3) is subject to paragraph 2.9.4—3(2)(c).

The other submitter comments regarding caffeine concentration limits for FSSF in powder and liquid form are responded to in Table 2, Appendix 1 to this report. These comments did not result in changes to the drafting.

Packaging requirements for solid and semi-solid FSSF in a multi-pack

Section 2.2.4 of the 2nd CFS outlines the evidence and rationale for requiring individual wrapping of all solid and semi-solid individual portions 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.

Regarding the suggestion to reword the reference to ‘small separate portions’ in the title of section 2.9.4—12 to focus on FSSF sold in multi-serve packages, FSANZ agrees with this

suggestion. FSANZ has updated the section 2.9.4—12 title to better reflect the intent that the requirement applies regardless of the size of the individual portion.

Regarding the recommendation to revise the drafting to indicate that each individual portion is intended to be consumed in one setting or within a day and to introduce a maximum caffeine limit of 200 mg per portion, FSANZ agrees. The intent of the drafting was that an individual portion that requires individual packaging should not contain more than the 200 mg one-day quantity of caffeine. This ensures there is no confusion regarding the amount of caffeine consumed if the individual portion were to contain more than one serve. The drafting has been revised to ensure that each individually packaged portion in a multi-pack does not exceed the permitted one-day quantity of caffeine, regardless of the number of serves it contains (subsection 2.9.4—12(4)).

Regarding the issue of whether the wording 'more than 200 mg of caffeine in total' refers to an individual portion or the entire multi-pack, paragraph 2.9.4—12(1)(a) refers to the total amount of caffeine within the multi-pack. Note that as discussed above, subsection 2.9.4—12(4) has been amended to require that a separately packaged individual portion must not contain more than the permitted one-day quantity of caffeine. This addition will clarify the maximum amount of caffeine permitted in an individual portion and should assist in making clear that paragraph 2.9.4—12(1)(a) is referring to the entire contents of the multi-pack.

Regarding the issue of whether dissolvable strips should be regulated as food, determination of what is regulated as a food and what is regulated as a therapeutic is out of scope for this proposal and will be given further consideration in Proposal P1010. FSANZ has however expanded the example to include bars to better reflect the intent of the example that the requirement does not only apply to small volume products, as discussed above.

In the consultation paper, FSANZ proposed an exemption from certain caffeine-related labelling requirements for FSSF containing caffeine if the caffeine is present only from chocolate, cocoa, decaffeinated tea and/or coffee (including instant versions of these) (see section 2.3.8.1). Following release of the consultation paper, FSANZ has decided to also apply this exemption to the individual packaging requirement i.e. the individual packaging requirement set out in section 2.9.4—12 will not apply to solid and semi-solid individual portions 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, if the caffeine is present only from chocolate, cocoa, decaffeinated tea and/or coffee (including instant versions of these). If caffeine is present from any other source (in addition to or instead of these ingredients), the individual packaging requirement would apply.

FSANZ considers the regulatory impact of individual packaging on certain FSSF is not justified when caffeine is present only because of its natural occurrence in certain ingredients that have minimal amounts of caffeine (cocoa, chocolate and decaffeinated tea or coffee).

Chocolate and cocoa contain low levels of caffeine (approximately 10 mg in a 50 g bar of plain milk chocolate and 11 mg in 5 g of cocoa powder). Decaffeinated tea and/or decaffeinated coffee contain no to negligible levels of caffeine (maximum levels are prescribed in Standard 2.10.4 of the Code) and would therefore contribute minimal amounts of caffeine when used as an ingredient in a FSSF. The approach is more risk proportionate than that proposed in the 2nd CFS and reduces the regulatory burden of individual packaging when caffeine is only present from the use of these foods.

Other ingredients that contain caffeine by natural occurrence (e.g. tea, coffee) are not included in the exemption due to their higher caffeine content and therefore their potential to contribute more substantial amounts of caffeine to a FSSF compared to chocolate, etc.

Other submitter comments have been responded to in Table 2, Appendix 1 to this report. No changes relating to packaging requirements in FSSF have been made to the drafting based on those submitter comments.

2.3.7.4 Decision

For the reasons stated in this report, FSANZ reaffirmed its assessment that the Code should be amended to require:

- that FSSF must not contain caffeine in total, from any source, at a concentration of 5% or more if the food is in a powdered form
- that FSSF must not contain caffeine in total, from any source, at a concentration of 1% or more if the food is in a liquid form
- individual wrapping of all solid and semi-solid individual portions within a multi-pack of caffeine-containing FSSF, when the pieces require no further preparation, and the multi-pack contains more than a total of 200 mg caffeine. Individual packages cannot contain more than the 200 mg one-day quantity of caffeine.

These requirements are included in paragraph 2.9.4—3(3) and section 2.9.4—12 of the approved draft variation.

FSANZ has decided that the individual packaging requirements set out in 2.9.4—12 do not apply to a FSSF that contains caffeine only from one or more of the following:

a) cocoa
b) chocolate
c) decaffeinated coffee containing no more than 1 g/kg of anhydrous caffeine on a dry basis
d) decaffeinated tea containing no more than 4 g/kg of anhydrous caffeine on a dry basis
e) decaffeinated instant coffee containing no more than 3 g/kg of anhydrous caffeine on a dry basis
f) decaffeinated instant tea containing no more than 3 g/kg of anhydrous caffeine on a dry basis.

The drafting has been revised to clarify that:

- the concentration limits for powder and liquid apply to caffeine from any source (see subsection 2.9.4—3(3) of the variation)
- the individual packaging requirement applies to solid and semi-solid FSSF of any size, not only small volume FSSF (see section 2.9.4—12 of the variation)
- individual packages within the multi-pack cannot contain more than the 200 mg one-day quantity of caffeine (see subsection 2.9.4—12(4) of the variation).

2.3.8 Labelling of formulated supplementary sports foods containing caffeine

2.3.8.1 Labelling when caffeine is present from certain ingredients in FSSF

2nd CFS

In the 2nd CFS, FSANZ proposed the following new labelling requirements for FSSF containing caffeine[16]:

[16] These are the requirements relevant to this section – the development of these and other labelling

- an advisory statement using wording to the effect of ‘contains caffeine’
- declaration in the NIP of the average quantity of caffeine present (section 2.9.4—11)
- an alternative warning statement (to the warning statement already required on the label of FSSF) for FSSF containing caffeine that specifies it is not suitable for children under 15 years of age, or pregnant *or breastfeeding* women (subparagraph 2.9.4—4(1)(a)(iv)).

It was proposed that these labelling requirements applied irrespective of the source or amount of caffeine present in the FSSF.

Some submissions received in response to the 2nd CFS questioned whether the labelling requirements should apply if the caffeine in a FSSF was below a certain level or from a particular source.

Consultation paper

FSANZ considered this issue as outlined in Table 5 of the consultation paper released for public comment in October 2025 (FSANZ, 2025b)) and in Appendix 2 of this report.

Following consideration of submitter comments, in the consultation paper FSANZ proposed an exemption for FSSF containing caffeine from the new caffeine-related labelling requirements if the caffeine is present only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee (including instant versions of these). For these FSSF and for FSSF that do not contain caffeine, the existing warning statement under Standard 2.9.4 is required: *Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision*. If caffeine is present from any other source (in addition to or instead of these ingredients), the caffeine-related labelling would be required.

Submitters supported the approach proposed in the consultation paper for the exemption. Some submitters suggested the exemption should be extended to include other low-caffeine ingredients, coffee and tea or apply a minimum caffeine threshold for labelling requirements to avoid over-regulation. Some submitters were concerned that drafting for this exemption in the proposed draft variation was not clear. These suggestions and the FSANZ responses are provided in Table 2, Appendix 1 of this report.

Discussion

FSANZ has decided to maintain the proposed approach of exempting FSSF containing caffeine from the new caffeine-related labelling requirements if the caffeine is present only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee (including instant versions of these). If caffeine is present from any other source (in addition to or instead of these ingredients), the caffeine-related labelling would be required. In response to submitter feedback, FSANZ has revised the draft variation proposed in the consultation paper to clarify the application of the exemption (see sections 2.9.4—4, 2.9.4—11 and 2.9.4—12 of the approved draft variation).

FSANZ has not developed a caffeine threshold below which FSSFs would be exempt from caffeine-related labelling requirements, as suggested by some submitters, because it is difficult to determine a scientifically valid technological or pharmacological basis for such a limit. Instead, FSANZ considers the approach that was proposed is a more pragmatic way of achieving the same outcome as setting a threshold. FSANZ considers that if caffeine itself is added as an ingredient to a FSSF, it would be added in amounts high enough to achieve an

requirements relating to the risk management of caffeine in the food supply is outlined in the following sections.

ergogenic effect. An exemption from the caffeine-related labelling requirements for caffeine itself, including a threshold limit, is therefore not appropriate or necessary.

FSANZ considers the regulatory impact of caffeine-related labelling on FSSF is not justified when caffeine is present only because of its natural occurrence in certain ingredients that have minimal amounts of caffeine (cocoa, chocolate and decaffeinated tea or coffee).

The approach is more risk proportionate than that proposed in the 2nd CFS and reduces the regulatory burden of labelling when caffeine is only present from the use of these foods. It also aligns with the regulatory approach for labelling of other foods containing chocolate, cocoa, decaffeinated tea or decaffeinated coffee. The approach is consistent with the approach in the 2nd CFS for FSSF that contain ingredients commonly associated with caffeine (including coffee and tea). In these cases, consumers are still advised of the actual amount of caffeine present.

Additional justification for the exemption is provided in section 2.3.7 above.

Decision

The approved draft variation provides that caffeine related labelling requirements (listed below) do not apply to a FSSF that contains caffeine only from one or more of the following:

a) cocoa
b) chocolate
c) decaffeinated coffee containing no more than 1 g/kg of anhydrous caffeine on a dry basis
d) decaffeinated tea containing no more than 4 g/kg of anhydrous caffeine on a dry basis
e) decaffeinated instant coffee containing no more than 3 g/kg of anhydrous caffeine on a dry basis
f) decaffeinated instant tea containing no more than 3 g/kg of anhydrous caffeine on a dry basis.

The caffeine related labelling requirements for FSSF that this exemption applies to are:

an advisory statement using wording to the effect of 'contains caffeine' as required under subparagraph 2.9.4—4(1)(a)(iv)(A) and 2.9.4—12(5)
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* (subparagraph 2.9.4—4(1)(a)(iv)(B))
declaration in the NIP of the average quantity of caffeine present (section 2.9.4—11).

If the FSSF for retail sale does not contain caffeine or contains caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee (including instant versions of these), it must be labelled with the existing warning statement already required under Standard 2.9.4: *Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision.*

2.3.8.2 Exemptions from labelling for foods for retail sale, and foods sold to a caterer

Currently under the Code, where a FSSF for retail sale is exempt from the requirement to bear a label, there are no requirements for the labelling information required under Standard 2.9.4 to be provided by another means. FSANZ considers there would not be many situations in which FSSF for retail sale would be exempt from the requirement to bear a label. The provision of information for FSSF for retail sale that are exempt from the

requirement to bear a label will be considered more broadly under P1010.

For FSSF containing caffeine sold to a caterer, currently under Standard 1.2.1, certain information required in relation to FSSF would have to be on the label of that FSSF or provided to the caterer. The provision of information for FSSF sold to caterers will also be considered more broadly under P1010.

The following sections therefore apply to FSSF for retail sale that are not exempt from the requirement to bear a label, unless otherwise stated.

2.3.8.3 Advisory statement 'contains caffeine'

1st and 2nd CFS

In the 1st and 2nd CFS, for the reasons stated in those reports (FSANZ 2022, 2025), FSANZ proposed a requirement for an advisory statement using wording to the effect of 'contains caffeine' on the label of all FSSF containing caffeine.

In the proposed draft variation in the 2nd CFS, the requirement for the advisory statement was included in the table in section S9—2 of Schedule 9 and relied on the existing requirement in subsection 1.2.3—2(1) for advisory statements in that table (see Attachment C to this report).

Submitter feedback to the 2nd CFS

Submitters supported the proposed approach to require the advisory statement using wording to the effect of 'contains caffeine' on the label of FSSF containing caffeine, except where caffeine was present from certain ingredients or below certain levels, as outlined in section 2.3.8.1 above.

Consultation paper

In the proposed draft variation in the consultation paper, the requirement for the advisory statement was included in Standard 2.9.4 rather than Standard 1.2.3 and Schedule 9 (as drafted in the draft variation in the 2nd CFS). This change was made for consistency with the current approach in the Code, whereby required statements and other information specifically required on the label of FSSF only are included in Standard 2.9.4. As noted above, the provision of information for FSSF for retail sale that are exempt from the requirement to bear a label will be considered more broadly under P1010.

Discussion

FSANZ has decided to maintain the requirement for an advisory statement using wording to the effect of 'contains caffeine' on the label of FSSF containing caffeine. FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee (including instant versions of these) will be exempt from the requirement for this advisory statement as outlined in section 2.3.8.1 above.

Given the risks associated with consumption of caffeine for different population groups (refer to section 2.2.1 above), it is important that consumers are alerted to the presence of caffeine in FSSF via the advisory statement.

The actual wording of the advisory statement is not prescribed, consistent with the current approach for advisory statements in Standards 1.2.1 and 1.2.3 of the Code.

The requirement is consistent with the current requirement for an advisory statement on

other foods with specific permission to contain added caffeine, i.e. cola-type beverages and FCBs, and foods containing guarana or extracts of guarana.

The requirement for labelling of individually wrapped portions of FSSF sold within a bulk package with an advisory statement is discussed in section 2.3.8.5 below.

Decision

The approved draft variation will amend the Code to require an advisory statement using wording to the effect of 'contains caffeine' on the label of FSSF containing caffeine for retail sale that are required to bear a label under Standard 1.2.1. The requirement for this advisory statement will not apply to FSSF that do not contain caffeine or contain caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee (including instant versions of these).

2.3.8.4 Warning statement

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 for retail sale unless exempt from the requirement to bear a label.

In the 1st CFS, FSANZ did not propose an additional warning statement or amendments to the existing warning statement for FSSF containing caffeine, as FSANZ considered it was appropriate to manage the risks associated with caffeine in these products.

After considering submitter comments, for reasons provided in the 2nd CFS, FSANZ proposed an alternative warning statement (to the warning statement already required on the label of FSSF) for FSSF containing caffeine. The wording of this warning statement was the same as that for the existing warning statement for FSSF except for the additional reference to breastfeeding women, i.e.:

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

Submitter feedback to the 2nd CFS

A number of submitters stated their support for the alternative warning statement proposed in the 2nd CFS.

Some submitters suggested amendments to the wording of the warning statement. These suggestions and the FSANZ responses are provided in Table 2, Appendix 1 of this report.

Some submitters questioned whether individual packages within an outer package would also require the warning statement, so consumers are alerted of the risk if the inner package is separated from the outer packaging.

Discussion

After considering submitter comments, FSANZ has decided to retain the wording of the warning statement for FSSF containing caffeine proposed in the 2nd CFS, i.e.:

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

This is an extension of the existing warning statement required for all FSSF to include breastfeeding women. The wording of the existing warning statement for FSSF is applicable to the risks from the consumption of caffeine identified from the risk assessment (section 2.2 above). The inclusion of breastfeeding women is based on evidence that a portion of caffeine circulating in the bloodstream enters breast milk and there is insufficient data to establish a health-based guidance value for breastfed infants for caffeine consumed via breastmilk. 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, the word 'breastfeeding' rather than 'lactating' must be used, to assist with consumer understanding.

FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee (including instant versions of these) will be exempt from the requirement for this warning statement as outlined in section 2.3.8.1 above but must be labelled with the existing warning statement required for FSSF.

There will be no specific requirement for individual packages within an outer package of FSSF to be labelled with the warning statement. This is because its length and prescriptive nature would be onerous in the context of small sized individual portions, and it does not explicitly refer to caffeine. The requirement for labelling of individually wrapped portions of FSSF sold within a bulk package is discussed in section 2.3.8.5 below.

Decision

The approved draft variation will amend the Code to require an alternative warning statement (to the warning statement already required for FSSF) for FSSF containing caffeine that are required to bear a label under Standard 1.2.1. This warning statement extends the existing warning statement to include breastfeeding women. The wording of the warning statement is as follows:

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

The wording of this warning statement is prescribed.

The requirement for this warning statement will not apply to FSSF that do not contain caffeine or contain caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee (including instant versions of these).

If the FSSF for retail sale does not contain caffeine or contains caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee (including instant versions of these), it must be labelled with the existing warning statement already required under Standard 2.9.4: *Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision.*

2.3.8.5 Labelling of individual portions

In the 2nd CFS, FSANZ proposed amending the Code to require individual wrapping of all solid and semi-solid individual portions (such as gummies and dissolvable strips) within a multi-pack of caffeine-containing FSSF when the pieces require no further preparation and the bulk packet contains more than a total of 200 mg caffeine from any source (see section 2.2.4 of the 2nd CFS). The labelling of these individual portions was not specifically discussed.

In response to that CFS, some submitters questioned whether individual packages within a multi-pack would require the warning statement, so consumers are alerted of the risk if the inner package is separated from the outer packaging. FSANZ considered this issue, as outlined in Table 6 of the consultation paper and in Appendix 2 of this report.

After considering submitter comments, and for the reasons set out in section 2.3.2.1 of the consultation paper, FSANZ proposed a labelling requirement for an advisory statement to the effect of 'contains caffeine' to be present on individual portions subject to the proposed requirement to be individually wrapped (see section 2.3.7 above).

FSANZ did not propose that this labelling requirement would apply to any other individual portion of FSSF within an outer package.

The proposed draft variation in the consultation paper also included a specific subsection requiring the advisory statement proposed for FSSF containing caffeine (see section 2.3.8.3 above) to also be on the outer package of the multi-pack of caffeine-containing FSSF. This additional subclause was required due to subsection 1.2.1—6(2) which states that if the food has more than one layer of packaging and it is required to bear a label, only one label is required in relation to that food. The proposed draft variation meant that the statement would be required on both the outer layer of packaging of the multi-pack and the individually wrapped portions, despite subsection 1.2.1—6(2). This approach ensures the advisory statement is available at all times to consumers, i.e. on the outer packaging at point of sale, and in the event the individually wrapped portion is separated from the outer packaging.

Submitter feedback from the consultation paper

There was broad support for requiring a caffeine advisory statement on individual portions of FSSF sold within multi-packs. Some submitters advocated that the requirement should apply to all FSSF containing caffeine in a multi-pack, including liquids and powders. Two submitters considered warning statements should also be mandated on individual portions, and one of these submitters recommended the requirement should be regardless of packaging size.

Several submitters sought confirmation of intent or clarity regarding specific aspects of the draft variation.

Submitter comments about the proposed approach and FSANZ responses are provided in table 2, Appendix 1 of this report.

Discussion

The proposed approach in the consultation paper, as outlined above, has been maintained.

The purpose of this requirement is to mitigate the risk that individually wrapped portions of caffeine-containing FSSF are inadvertently consumed by individuals sensitive to caffeine if they become separated from the outer packaging. Products that will be subject to the new labelling requirement include solid or semi-solid ready-to-eat FSSF, such as bars, chewables (e.g. gummies) and dissolvable strips, which present the highest risk of inadvertent consumption. The additional requirement for the advisory statement to also be on the outer package of the multi-pack of caffeine-containing FSSF has been retained for the reason outlined in the above section.

The labelling requirement will not apply to FSSF that are concentrated or ready-to-drink liquids and pre-workout powders packaged in individual sachets. Ready-to-drink liquids are likely to be fully labelled for retail sale, whereas concentrated liquids and pre-workout

powders are less palatable unless prepared according to instructions and are also less likely to resemble non-caffeinated general foods. Requirements for the caffeine advisory statement and warning statements as well as all other labelling required under Standards 1.2.1 and 2.9.4 will still apply to the multipack (i.e. legible at the point of sale) containing the individual portions. Additionally, FSSF in liquid and powder form will also be subject to maximum caffeine limits and concentration restrictions described in section 2.3.7 of this report.

The prescribed warning statement required for the outer packaging of caffeinated FSSF will not be required on individual portion labels due to space constraints and because it does not explicitly refer to caffeine. FSANZ considers the presence of the caffeine advisory statement is sufficient to alert consumers to the caffeinated nature of FSSF individual portions if they are separated from the outer packaging.

The draft variation proposed in the consultation paper has been amended to clarify that the advisory statements described above will not be required on FSSF that contain caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee, as outlined in section 2.3.8.1 above.

Decision

The approved draft variation will require an advisory statement to the effect that the food contains caffeine to be present on certain individual portions of FSSF:

- within an outer package subject to the requirement to be individually wrapped, and
- with a surface area of 30 cm^2 or greater.

The approved draft variation will also require the advisory statement (required under subparagraph 2.9.4—4(1)(a)(iv)(A)) to the effect that the food contains caffeine on the outer package of certain individual portions of FSSF:

- within an outer package subject to the requirement to be individually wrapped, and
- with a surface area of 30 cm^2 or greater.

These advisory statements will not be required for FSSF that contain caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee (including instant versions of these).

2.3.8.6 Declaration of amount of caffeine and one-day quantity

In the 1st and 2nd 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.

FSANZ also proposed a ‘one-day quantity’ for consumers, i.e. to not exceed 200 mg caffeine per day, as outlined in section 2.2.6 above. There are existing labelling requirements in the Code for FSSF 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). These instructions could not direct consumers to consume more than 200 mg per day of caffeine from that FSSF in order to meet the one-day quantity. FSANZ therefore did not propose any amendments to the existing labelling requirements for directions for use of FSSF in the 1st or 2nd CFS.

Submitter feedback to the 2nd CFS

Some submitters stated their support for the approach proposed, with no submitters opposing the approach, except where caffeine was present from certain ingredients or below certain levels, as outlined in section 2.3.8.1 above.

Submitter comments about the proposed approach and FSANZ responses are provided in Table 2, Appendix 1 of this report.

Discussion

FSANZ has decided to maintain the proposed approach as outlined above with one exception. FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee (including instant versions of these) will be exempt from the requirement for the average quantity of caffeine present in the NIP as outlined in section 2.3.8.1 above. If the FSSF contains caffeine from one of these ingredients in addition to caffeine from another source(s), caffeine present in the FSSF from all sources (including chocolate etc.) would need to be included in the declaration. The draft variation has been amended to clarify that in that situation, the average quantity of caffeine *from any source*, in a serving and in a unit quantity of the FSSF, must be stated in the NIP.

The declaration of caffeine content in the NIP (rather than elsewhere on the label) is consistent with the requirement to declare other biologically active substances in the NIP if a nutrition content or health claim is made. It also means the prescribed format of the NIP applies to the caffeine declaration, providing consistency across FSSF containing caffeine. The requirement to declare the average quantity of caffeine in the NIP means that such a declaration is not a nutrition content claim (subsection 1.1.2—9(2) of the Code).

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).

The requirement to declare the average quantity of caffeine will assist with preventing consumers from being misled by FSSF containing minimal or ineffective amounts of caffeine with respect to sports performance but labelled as containing caffeine in accordance with the advisory statement (see section 2.3.8.3), as they will be informed about the quantity present.

The existing labelling requirement for directions for use in Standard 2.9.4 will require the provision of appropriate information to advise consumers about the safe level of intake of a FSSF to not exceed the one-day quantity. The NIP declaration in conjunction with these directions for use enables enforcement of the one-day quantity requirement.

Decision

The approved draft variation will require the average quantity of caffeine from any source, in a serving and in a unit quantity (per 100 g or 100 mL) of the FSSF, to be stated in the NIP.

This information must be set out below the information about sodium and above any other nutrient or biologically active substance required by subparagraph 1.2.8—6(1)(d)(iv) (section 2.9.4—11 in the approved draft variation (Attachment A)).

This requirement will not apply to FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee (including instant versions of these).

3 Risk communication

3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this proposal. All calls for submissions are notified via the Food Standards Notification Circular, media release and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to assist consideration of the draft variation to the Code. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this proposal.

The draft variation was considered for approval by the FSANZ Board having regard to all submissions made during the call for submissions period.

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 will be updated to ensure consistency with the new requirements for caffeine in food.

Based on feedback from submissions to the 2nd CFS and the consultation paper 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 food regulation system partners to ensure consistency of information and to maximise the effectiveness of available resources.

3.3 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

There are no 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, FSANZ made notifications to the WTO in accordance with the WTO Agreement on Technical Barriers to Trade and on the Application of Sanitary and Phytosanitary Measures. See section 2.1.3 above for further information and Appendix 3, Table 1 for submitter comments and FSANZ response.

4 FSANZ Act assessment requirements

4.1 Section 59

4.1.1 Consideration of costs and benefits

As required by paragraph 59(a) of the FSANZ Act, FSANZ had regard to whether the costs that would arise from the proposal outweigh the direct and indirect benefits.

FSANZ also met impact analysis requirements applying to national standards setting bodies[17]. FSANZ reviewed its assessment of costs and benefits in light of feedback received in response to all submissions and prepared a Decision Regulation Impact Statement (DRIS; see SD5). The DRIS contains FSANZ's analysis of:

- the costs and benefits
- broader impact analysis questions, to meet impact analysis requirements.

The Office of Impact Analysis has assessed the quality of the regulatory impact analysis in the DRIS as compliant with impact analysis guidelines, containing an adequate level of analysis that is commensurate with the significance of the impacts.

The DRIS analyses 2 options to address the problems:

1. Maintaining the status quo (rejecting the draft variations)
2. Regulatory change through amendments to the Code.

The net benefit of status quo (option 1) by definition is zero, as it involves no change.

FSANZ has not been able to quantify all the costs or any of the benefits for this proposal. This makes assessing whether there is a net benefit difficult.

However, almost all costs for FSSF have been quantified, which are the most significant costs for the proposal overall. This enables a break-even analysis to be calculated for the FSSF related aspects of the proposal.

The break-even analysis shows that consumers, government and/or industry will need to receive benefit at the amount of $0.26 to $0.52 per year per daily user of caffeinated FSSF (5.3% of adult population in Australia and NZ) for the benefits of the proposal to exceed the quantified costs.

Put differently, the analysis shows that consumers, government and/or industry will need to receive benefit at the amount of $294,532 to $583,856 per year over 10 years for the benefits of the proposal to exceed the quantified cost.

FSANZ considers it is likely that this benefit will be achieved.

For the full analysis, refer to the DRIS at SD5. The assessment concluded that the direct and indirect benefits to the community, government and industry that would arise from amending the Code as proposed in option 2 are expected to outweigh the costs and return a net benefit.

[17] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis

4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the proposal.

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 1.4.4 above. Refer also to section 2.5.1 of the P1054 Amendment report (FSANZ 2020) and Appendix 1 of this report

4.1.4 Any other relevant matters

Other relevant matters are considered below.

4.2 Subsection 18(1)

FSANZ has also considered the 3 objectives in subsection 18(1) of the FSANZ Act during the assessment.

4.2.1 Protection of public health and safety

FSANZ has assessed the best available 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 labelling requirements for certain foods. The assessment indicates that risks exist to the health and safety of consumers (section 2.2). 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.

4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The current advisory statements required for a limited range of products that contain caffeine (see section 1.4.1 above) assist consumers to make informed choices about foods containing caffeine. FSANZ has also considered the labelling requirements for FSSF containing caffeine (see section 2.3.8 above) and high caffeine coffee beverages (see section 2.3.5) with respect to the provision of adequate information relating to food to enable consumers to make informed choices.

4.2.3 The prevention of misleading or deceptive conduct

FSANZ has not identified any relevant issues.

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 evidence. 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 scientific evidence 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 1.4.5 for a discussion on 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.

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. Consistent with Australia's and New Zealand's obligations under the WTO, FSANZ has made a notification under the TBT and SPS agreements (section 3.3).

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

FSANZ has not identified any issues in relation to the promotion of fair trading in food.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

FSANZ must have regard to any written policy guidelines formulated by the Food Ministers' Meeting (formerly the Australia and New Zealand Ministerial Forum on Food Regulation[18]). There are 3 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
- 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 approving the draft variation. FSANZ considers that that assessment and the approved draft variation address each.

5 Transitional arrangements

The approved draft variation provides transitional arrangements. In developing these transitional arrangements, FSANZ considered the risk to public health and safety, the

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

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.

For the reasons outlined in the 2nd CFS (section 3.1.1), FSANZ proposed a transition period of 2 years beginning 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. 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.

5.1 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 established to protect public health and safety.

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.

FSANZ notes that some industry stakeholders requested up to 4 years for the transitional period based on the revisions to the draft variation relating to guarana extract. After providing further clarification on the compositional parameters for guarana extract in the draft variation, FSANZ considers an extension to the transition period is not needed as the regulatory impact of the prohibition is expected to be limited.

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Attachments

A. Approved draft variations to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement
C. Draft variations to the *Australia New Zealand Food Standards Code* (call for submissions)
D. Draft variations to the *Australia New Zealand Food Standards Code* (consultation paper)

Attachment A – Approved 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—a *prescribed caffeine product.

[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 from any source.

Example A food for retail sale that contains caffeine as an ingredient or component as a result of the addition of caffeine (1,3,7-trimethylxanthine) or of a plant extract including but not limited to guarana extract.

[3] After subsection 1.1.1—10(7)

Insert:

Examples Caffeine present in a food for sale, or in an ingredient of a food for sale, as a result of the addition of cocoa, chocolate, coffee or tea; is caffeine that is in the food for sale or the ingredient by natural occurrence. The caffeine occurs naturally in the cocoa, chocolate, coffee or tea.

Caffeine present in a food for sale, or in an ingredient of a food for sale, as a result of the addition of caffeine (1,3,7-trimethylxanthine) is not caffeine in the food for sale or the ingredient by natural occurrence.

(7A) Subsection (7) does not apply to caffeine present in a food for sale, or in an ingredient of a food for sale, as a result of the addition of guarana extract.

Standard 1.1.2 Definitions used throughout the Code

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

Repeal the paragraph, substitute:

(e) subparagraph 2.9.4—4(1)(a)(iii), sub-subparagraph 2.9.4—4(1)(a)(iv)(B) or subparagraph 2.9.4—4(1)(a)(v) (warning statements for formulated supplementary sports food).

[5] Subsection 1.1.2—2(3)

Insert:

prescribed caffeine product means any of the following:

(a) caffeine (1,3,7-trimethylxanthine);

(b) guarana extract.

[6] Subsection 1.1.2—3(2)

Insert:

guarana extract means a product that:

(a) is produced from guarana seeds by use of an extraction process; and

(b) contains caffeine at a concentration of:

(i) 5% or more—if the product is in a solid or semi-solid form; or

(ii) 1% or more—if the product is in a liquid form.

[7] Subsection 1.1.2—3(2)

Insert:

high caffeine coffee beverage means a food for retail sale that:

(a) is a beverage; and

(b) is in a package; and

(c) *bears a label with a *nutrition information panel; and

(d) contains coffee; and

(e) contains no less than 200 mg caffeine per serving; and

(f) is not one of the following:

(i) a formulated caffeinated beverage;

(ii) a formulated supplementary sports food.

Standard 1.2.1 Requirements to have labels or otherwise provide information

[8] Paragraph 1.2.1—8(1)(za)

Repeal the paragraph, substitute:

(za) for *prescribed beverages—an energy statement (see section 2.7.1—4A);

(zb) for high caffeine coffee beverages:

(i) declarations of *average quantities (see subsection 2.10.4—3A(1)); and

(ii) advisory statements (see subsection 2.10.4—3A(2)).

[9] Subsection 1.2.1—8(3)

Repeal the subsection, substitute:

(3) For subsection 1.2.1—6(3), the information is:

(a) *warning statements and declarations in accordance with sections 1.2.3—3 and 1.2.3—4; and

(b) advisory statements in accordance with subsection 2.10.4—3A(2).

Standard 1.5.1 Novel foods

[10] At the end of section 1.5.1—3

Add:

(3) Despite any other provision of this Code, a food for retail sale must not have as an ingredient or component, caffeine from a novel food unless:

(a) the novel food is listed in the table to section S25—2; and

(b) any conditions of use specified in the corresponding row of that table are

complied with.

Standard 2.9.4 Formulated supplementary sports foods

[11] 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.

[12] 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.

[13] At the end of section 2.9.4—3

Add:

(3) Subject to paragraph 2.9.4—3(2)(c), formulated supplementary sports food must not contain caffeine in total, from any source, at a concentration of:

(a) 5% or more—if the food is in a powdered form; and

(b) 1% or more—if the food is in a liquid form.

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

Repeal the subparagraphs, substitute:

(iii) if the food is a food to which subsection (3) applies—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 is a food to which subsection (4) applies:

(A) an advisory statement to the effect that the food contains caffeine; and

(B) 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

[15] After subsection 2.9.4—4(2)

Add:

(3) This subsection applies to the following foods:

(a) a formulated supplementary sports food that does not contain caffeine;

(b) a formulated supplementary sports food that contains caffeine only from any of the following:

(i) cocoa:

(ii) chocolate;

(iii) decaffeinated coffee containing no more than 1 g/kg of anhydrous caffeine on a dry basis;

(iv) decaffeinated tea containing no more than 4 g/kg of anhydrous caffeine on a dry basis;

(v) decaffeinated instant coffee containing no more than 3 g/kg of anhydrous caffeine on a dry basis;

(vi) decaffeinated instant tea containing no more than 3 g/kg of anhydrous caffeine on a dry basis.

(4) This subsection applies to a formulated supplementary sports food that contains caffeine other than caffeine from any of the following.

(a) cocoa:

(b) chocolate;

(c) decaffeinated coffee containing no more than 1 g/kg of anhydrous caffeine on a dry basis;

(d) decaffeinated tea containing no more than 4 g/kg of anhydrous caffeine on a dry basis;

(e) decaffeinated instant coffee containing no more than 3 g/kg of anhydrous caffeine on a dry basis;

(f) decaffeinated instant tea containing no more than 3 g/kg of anhydrous caffeine on a dry basis.

[16] After section 2.9.4—10

Add:

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

(1) Subject to subsection (2), this section applies to a formulated supplementary sports food that contains caffeine.

(2) This section does not apply to a formulated supplementary sports food that contains caffeine only from any of the following:

(a) cocoa:

(b) chocolate;

(c) decaffeinated coffee containing no more than 1 g/kg of anhydrous caffeine on a dry basis;

(d) decaffeinated tea containing no more than 4 g/kg of anhydrous caffeine on a dry basis;

(e) decaffeinated instant coffee containing no more than 3 g/kg of anhydrous caffeine on a dry basis;

(f) decaffeinated instant tea containing no more than 3 g/kg of anhydrous caffeine on a dry basis.

(3) The nutrition information panel for the formulated supplementary sports food must state the *average quantity of caffeine from any source in:

(a) a serving of the food; and

(b) a *unit quantity of the food.

(4) The information required in subsection (3) 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 in a multi-pack

(1) Subject to subsection (2), 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 bars, chewables or dissolvable strips

(2) This section does not apply to a formulated supplementary sports food that contains caffeine only from any of the following:

(a) cocoa:

(b) chocolate;

(c) decaffeinated coffee containing no more than 1 g/kg of anhydrous caffeine on a dry basis;

(d) decaffeinated tea containing no more than 4 g/kg of anhydrous caffeine on a dry basis;

(e) decaffeinated instant coffee containing no more than 3 g/kg of anhydrous caffeine on a dry basis;

(f) decaffeinated instant tea containing no more than 3 g/kg of anhydrous caffeine on a dry basis.

(3) The advisory statement required by sub-subparagraph 2.9.4—4(1)(a)(iv)(A) must be on a label on the outer package of the formulated supplementary sports food.

(4) Each individual portion must be separately packaged.

(5) Each individual portion must not contain more than 200 mg caffeine in total, from any source.

(6) Each individual portion with a surface area of 30 cm^2 or greater must *bear a label, with an advisory statement to the effect that the food contains caffeine.

(7) In this section, ***each individual portion*** means an individual portion referred to in paragraph (1)(c).

Standard 2.10.4 Miscellaneous standards for other foods

[17] Note to section 2.10.4—2

Insert:

high caffeine coffee beverage means a food for retail sale that:

(a) is a beverage; and

(b) is in a package; and

(c) *bears a label with a *nutrition information panel; and

(d) contains coffee; and

(e) contains no less than 200 mg caffeine per serving; and

(f) is not one of the following:

(i) a formulated caffeinated beverage;

(ii) a formulated supplementary sports food.

[18] After section 2.10.4—3

Add:

2.10.4—3A Labelling requirements—high caffeine coffee beverages

Required declarations

(1) For the labelling provisions, the required declaration of *average quantity is a declaration in the *nutrition information panel of the average quantity of caffeine from any source, expressed in milligrams, in:

(a) a serving of the food; and

(b) a *unit quantity of the food.

Note The labelling provisions are set out in Standard 1.2.1.

Required advisory statements

(2) For the labelling provisions, the required advisory statements are statements to the effect that:

(a) the food is high in caffeine; and

(b) the food is not suitable for:

(i) children under 15 years of age; or

(ii) pregnant or breastfeeding women.

Note The labelling provisions are set out in Standard 1.2.1.

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Proposal P1056 – Caffeine review) Variation

1. Authority

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

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

The Authority prepared Proposal 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 approved a draft variation – the *Food Standards (Proposal P1056 – Caffeine review) Variation* (approved draft variation).

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

2. Variation is a legislative instrument

The approved draft variation is 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).

This instrument is not 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 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 approved a 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 approved draft variation also makes other amendments to the Code as a consequence of the above amendments.

4. Documents incorporated by reference

The approved 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 included 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. The second call for submissions was issued on 4 March 2025 and ended on 15 April 2025.

After consideration of submissions to the second call for submissions, FSANZ sought submissions on amendments to the draft variation proposed in the second call for submissions via a public consultation paper from 31 October to 12 December 2025.

Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

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. The OIA was satisfied that the function of a CRIS will be achieved through the consultation undertaken by FSANZ under the FSANZ Act (CRIS reference number: OIA24-07750). A Decision Regulation Impact Statement (DRIS) was prepared by the Authority and the DRIS has been assessed by the OIA as compliant (DRIS reference number: OBPR22-03666).

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

References to 'the variation' in this section are taken to be references to the approved 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 of the variation provides a transitional arrangement.

Subclause 4(1) provides that the stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 does not apply to any of the amendments made by the variation.

Instead, subclauses 4(2) and (3) provide a transitional arrangement where during a 24 month transition period commencing on the date of gazettal of the variation, a food product may be sold if the product complies with either: the Code as in force without the amendments made by the variation; or the Code as amended by the variation.

8. Schedule to the variation

Standard 1.1.1 – Structure of the Code and general provisions

Items [1] to **[3]** of the Schedule to the variation amend Standard 1.1.1 of the Code.

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

I**tems [1]** and **[2]** amend section 1.1.1—10.

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

Item [1] amends paragraph 1.1.1—10(5)(g) by repealing the paragraph and substituting it with an amended paragraph 1.1.1—10(5)(g).

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

The current paragraph 1.1.1—10(5)(g) prohibits – except where expressly permitted by the Code – a 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.

This paragraph is repealed and substituted with an amended paragraph.

Amended paragraph 1.1.1—10(5)(g) refers instead to: ‘if the food is for retail sale—a *prescribed caffeine product.’.

The amended paragraph prohibits a *prescribed caffeine product* being a food for retail sale unless expressly permitted by the Code. This is a new prohibition.

Subsection 1.1.2—2(3) of the Code defines what is a *prescribed caffeine product* for the purposes of paragraph 1.1.1—10(5)(g). The definition lists caffeine (1,3,7-trimethylxanthine) and *guarana extract* as prescribed caffeine products. This definition is a new definition in Standard 1.1.2 (see **Item [5]** of the Schedule below).

The effect of the above is to prohibit caffeine (1,3,7-trimethylxanthine) and *guarana extract* being a food for retail sale or sold as a food at retail sale unless that sale is expressly permitted by the Code.

Guarana extract is defined in Standard 1.1.2 (see **item [6]** below).

Item [2] amends 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) followed by an example.

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

Amended paragraph 1.1.1—10(6)(j) is identical to the existing paragraph 1.1.1—10(6)(j) except the amended paragraph ends in a semi-colon (;) and not a full stop. The existing paragraph is the last entry for subsection 1.1.1—10(6) and as such, it currently 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 from any source.’.

The proposed amendment prohibits a food for retail sale from having caffeine from any source as an ingredient or a component—unless expressly permitted by the Code. This is a new prohibition.

The example inserted after paragraph 1.1.1—10(6)(k) is an example of a food for retail sale having caffeine as an ingredient or a component. The example is:

- A food for retail sale that contains caffeine as an ingredient or component as a result of the addition of caffeine (1,3,7-trimethylxanthine) or of a plant extract including but not limited to *guarana extract*.

Guarana extract is defined in Standard 1.1.2 (see **item [6]** below).

Item [3] inserts the following after subsection 1.1.1—10(7):

two examples for the purposes of that subsection, and
new provision - subsection 1.1.1—10(7A).

Subsection 1.1.1—10(7) provides an exemption to the prohibitions imposed by subsection 1.1.1—10(6). Subsection 1.1.1—10(7) states that subsection 1.1.1—10(6) does not apply to a substance that is in a food for sale, or in an ingredient of a food for sale, by natural occurrence.

The term ‘natural occurrence’ is not defined in the Code and is to be given its ordinary meaning.

The examples inserted after subsection 1.1.1—10(7) relate to caffeine present as an ingredient in a food for sale and is provided for the purposes of new paragraph 1.1.1—10(6)(k).

Paragraph 1.1.1—10(6)(k) prohibits a food for retail sale from having caffeine as an ingredient or a component of a food for sale—unless expressly permitted by the Code. Subsection 1.1.1—10(7) provides that paragraph 1.1.1—10(6)(k) does not apply to caffeine in a food for sale, or in an ingredient of a food for sale, by natural occurrence.

The first example explains:

- Caffeine present in a food for sale, or in an ingredient of a food for sale, as a result of the addition of cocoa, chocolate, coffee or tea; is caffeine that is in the food for sale or the ingredient by natural occurrence. The caffeine occurs naturally in the cocoa, chocolate, coffee or tea. Subsection 1.1.1—10(7) will therefore apply to and exempt that caffeine from the prohibition imposed by new paragraph 1.1.1—10(6)(k).

The second example explains:

- Caffeine in a food for sale, or in an ingredient of a food for sale, as a result of the addition of caffeine (1,3,7-trimethylxanthine) is not caffeine in the food for sale or the ingredient by natural occurrence. The caffeine does not occur naturally in the food for sale or the ingredient of the food for sale. Subsection 1.1.1—10(7) will therefore not apply and that caffeine will not be exempt from the prohibition imposed by new paragraph 1.1.1—10(6)(k).

New subsection 1.1.1—10(7A) states that subsection 1.1.1—10(7) does not apply to caffeine present in a food for sale, or in an ingredient of a food for sale, as a result of the addition of *guarana extract*. The new subsection makes clear that caffeine from *guarana extract* in a food for retail sale is subject to the requirement imposed by new paragraph 1.1.1—10(6)(k). It is not exempted by subsection 1.1.1—10(7).

Guarana extract is defined in Standard 1.1.2 (see **item [6]** below).

Standard 1.1.2 – Definitions used throughout the Code

Items [4] to **[7]** of the Schedule to the variation amends 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.

Item [4] amends 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. Paragraph (e) of this definition refers to subparagraph 2.9.4—4(1)(a)(iii) or 2.9.4—4(1)(a)(iv), which relates to warning statements for formulated supplementary sports food.

Item [4] repeals paragraph (e) and substitutes the repealed paragraph with a new paragraph (e). New paragraph (e) refers to subparagraphs 2.9.4—4(1)(a)(iii) and 2.9.4—4(1)(a)(v); as well as sub-subparagraph 2.9.4—4(1)(a)(iv)(B).

This amendment is consequential to the amendment proposed in **item [14],** which amends

existing requirements in paragraph 2.9.4—4(1)(a) for warning statements on formulated supplementary sports foods; and adds a new requirement for an alternative warning statement on such foods (see **item [14]** below for details).

The effect of the amendment in **item [4]** is that the definition of *warning statement* in Standard 1.1.2 includes the new warning statement required in paragraph 2.9.4—4(1)(a).

Item [5] inserts a new definition into subsection 1.1.2—2(3): the definition of *prescribed caffeine product*.

The new definition states that *prescribed caffeine product* means any of the following: caffeine (1,3,7-trimethylxanthine), and guarana extract.

This amendment is related to the amendment in **item [1]** above.

Item [6] inserts a new definition into subsection 1.1.2—3(2): the definition of *guarana extract*. This new definition states that *guarana extract* means a product that:

(a) is produced from guarana seeds by use of an extraction process; and
(b) contains caffeine at a concentration of:
    (i) 5% or more—if the product is in a solid or semi-solid form; and
    (ii) 1% or more—if the product is in a liquid form.

The reference to products in solid or semi-solid form includes powdered forms.

This amendment is related to the amendments in **items [3]** and **[5].**

Item [7] inserts a new definition to subsection 1.1.2—3(2): the definition of *high caffeine coffee beverage*.

The new definition states that *high caffeine coffee beverage* means a food for retail sale that:

(a) is a beverage, and
(b) is in a package, and
(c) bears a label with a nutrition information pane, and
(d) contains coffee, and
(e) contains no less than 200 mg caffeine per serving, and
(f) is not a formulated caffeinated beverage nor a formulated supplementary sports food.

This amendment is related to the amendment in **item [8]** and **[17]** below.

Standard 1.2.1 – Requirements to have labels or otherwise provide information

Items [8] and **[9]** amend section 1.2.1—8.

Subsection 1.2.1—6(1) of the Code provides that, if a food for retail sale is in a package, it must *bear a label* with the information referred to in subsection 1.2.1—8(1) unless certain exemptions apply.

Bear a label is defined in Standard 1.1.2 of the Code.

Item [8] repeals paragraph 1.2.1—8(1)(za) and substitutes the repealed paragraph with an

amended paragraph (za) and a new paragraph (zb)

Amended paragraph 1.2.1—8(1)(za) is identical to the existing paragraph 1.2.1—8(1)(za) except the amending paragraph ends in a semi-colon (;) and not a full stop. The existing paragraph is the last entry for subsection 1.2.1—8(1) and, as such, currently ends in a full stop. To insert new paragraph 1.2.1—8(1)(zb) – paragraph 1.2.1—8(1)(za) must be amended so it ends in a semi-colon instead.

New paragraph 1.2.1—8(1)(zb) lists the following required information for high caffeine coffee beverages: declarations of average quantities in accordance with subsection 2.10.4—3A(1); and advisory statements in accordance with subsection 2.10.4—3A(2).

Subsection 1.1.2—2(3) sets out a definition of *average quantity* of a substance in a food. The definition states that *average quantity* of a substance in a food means the average, for such foods from that producer or manufacturer, of: (a) where a serving or reference amount is specified—the amount of the substance that such a serving or reference amount contains; or (b) otherwise—the proportion of that substance in the food, expressed as a percentage.

This amendment is related to the amendment proposed in **item [18]** below.

Item [9] repeals subsection 1.2.1—8(3) and substitutes the repealed subsection with an amended subsection 1.2.1—8(3).

Subsection 1.2.1—8(3) lists the information that subsection 1.2.1—6(3) requires be stated on the label of certain individual portion packs sold as part of a packaged food for retail sale. In existing subsection 1.2.1—8(3), the types of information required are the warning statements and declarations made in accordance with sections 1.2.3—3 and 1.2.3—4 respectively.

Amended subsection 1.2.1—8(3) includes a reference to subsection 2.10.4—3A(2), thereby requiring advisory statements required by subsection 2.10.4—3A(2) to also be included on the label of the individual portion packs for retail sales of food.

This amendment is also related to the amendment in **item [18]** below.

Standard 1.5.1 – Novel foods

Items [9] of the Schedule to the variation amend Standard 1.5.1 of the Code, by inserting new subsection 1.5.1—3(3) into that Standard. The new subsection is added at the end of section 1.5.1—3.

Standard 1.1.1 provides that a food for retail sale must not be, or have as an ingredient or component, a novel food unless expressly permitted by the Code. Standard 1.5.1 sets out when and how a novel food is permitted for this purpose. Section 1.1.2—8 of the Code defines what is a novel food for the purposes of the Code.

New subsection 1.5.1—3(3) provides that, despite any other provision of the Code, a food for retail sale must not have as an ingredient or component, caffeine from a novel food unless that novel food has been listed in the table to section S25—2 of the Code as a permitted novel food and any conditions of use specified in that section for that food are complied with.

The amendment clarifies that a provision in the Code permitting a food for retail sale to contain caffeine from any source as an ingredient or component does not extend to a novel food containing caffeine (unless that novel food is listed in the table to section S25—2 of the Code). Premarket assessment and approval as a novel food will therefore also be required.

Standard 2.9.4 – Formulated supplementary sports foods

Items [11] to **[16]** of the Schedule to the variation amend 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.

Items [11] to **[13]** amend section 2.9.4—3.

Section 2.9.4—3 sets compositional requirements for formulated supplementary sports food. Subsection 2.9.4—3(1) list substances that formulated supplementary sports food may contain.

Item [11] amends 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).

Amended subparagraph 2.9.4—3(1)(c)(ii) is identical to the existing subparagraph 2.9.4—3(1)(c)(ii) except the amended subparagraph ends in a semi-colon (;) and not a full stop. The existing subparagraph is the last entry for subsection 2.9.4—3(1) and, as such, currently ends in a full stop. To insert new paragraph 2.9.4—3(1)(d) – the subparagraph must be amended so it ends in a semi-colon instead.

New paragraph 2.9.4—3(1)(d) refers to ‘caffeine’ as a substance that formulated supplementary sports food may contain.

The effect of the amendment is that formulated supplementary sports food *may* contain (among other things) caffeine in accordance with the Code i.e., the addition of caffeine in a formulated supplementary sports food by a food business is voluntary.

However, if a food business adds caffeine to a formulated supplementary sports food—the food business must comply with all relevant compositional and labelling requirements in Standard 2.9.4 (see, for example, the new requirements in **item [15]** below).

Item [12] amends 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) sets out what a 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 subsection 1.1.2—2(3) of the Code as meaning the amount of that food which is to be consumed in one day in accordance with directions specified in the label.

Amended paragraph 2.9.4—3(2)(b) is identical to the existing paragraph 2.9.4—3(2)(b) except the amended paragraph ends in a semi-colon (;) and not a full stop. The existing paragraph is the last entry in subsection 2.9.4—3(2) and as such, 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.’.

The effect of the amendment in **item [12]** is that a formulated supplementary sports food must not contain, in a one-day quantity, (among other things) more than 200 mg of caffeine in total from any source.

'In total, from any source' includes all caffeine that is permitted by the Code to be present in the food. This includes caffeine present by natural occurrence (see **item [3]** above).

Item [13] inserts new subsection 2.9.4—3(3) into Standard 2.9.4.

Section 2.9.4—3 sets out compositional requirements for formulated supplementary sports food.

New subsection 2.9.4—3(3) sets a new compositional requirement for a formulated supplementary sports food, which is subject to paragraph 2.9.4—3(2)(c).

New subsection 2.9.4—3(3) prohibits formulated supplementary sports food from containing caffeine in total, from any source, at a concentration of:

- 5% or more for formulated supplementary sports food in a powdered form;
- 1% or more for formulated supplementary sports food in a liquid form.

New subsection 2.9.4—3(3) provides that this compositional requirement applies subject to paragraph 2.9.4—3(2)(c), which prohibits a formulated supplementary sports food from containing, in a one-day quantity, more than 200 mg of caffeine in total from any source.

Subsection 1.1.1—10(3) of the Code requires a food for sale - including formulated supplementary sports food – to comply with compositional requirements set by the Code – including by the new subsection – relating to this kind of food.

The intent of new subsection 2.9.4—3(3) is to prohibit the sale of powdered forms of FSSF containing caffeine at a concentration of 5% or more, or of liquid forms of FSSF containing caffeine at a concentration of 1% or more. These limits are commensurate with the safe maximum concentration limits identified in P1054.

Items [14] and **[15]** amend section 2.9.4—4.

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

Subsections 1.1.1—10(8) and 1.1.1—10(9) of the Code requires a food for sale - including formulated supplementary sports food – to comply with labelling and compositional requirements, which apply to that food.

Item [14] amends subparagraphs 2.9.4—4(1)(a)(iii) and (iv) by repealing those subparagraphs and substituting those subparagraphs with new 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 **item [4]** above).

Amended subparagraph 2.9.4—4(1)(a)(iii) instead states: 'if the food is a food to which subsection (3) applies – 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 is listed in new subsection 2.9.4—4(3) (see **item [15]** below).

Amended subparagraph 2.9.4—4(1)(a)(iv) states: 'if the food 'is a food to which subsection (4) applies:

(A) an advisory statement to the effect that the food contains caffeine; and
(B) 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'.

Amended subparagraph 2.9.4—4(1)(a)(iv) requires labelling for formulated supplementary sports food that contain caffeine other than caffeine from any of the sources listed in new subsection 2.9.4—4(4) (see **item [15]** below) to contain the following statements:

(A) an advisory statement to the effect that the food contains caffeine; and
(B) 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'.

New subparagraph 2.9.4—4(1)(a)(v) restates existing subparagraph 2.9.4—4(1)(a)(iv). It provides that: 'if the food contains added phenylalanine—the warning statement 'Phenylketonurics: Contains phenylalanine'. The existing paragraph had to be renumbered as a consequence of the other amendments to paragraph 2.9.4—4(1)(a) above.

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

The advisory statement and warning statements required by the amendments in **item [14]** 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 [15] inserts new subsections 2.9.4—4(3) and 2.9.4—4(4) into Standard 2.9.4.

New subsection 2.9.4—4(3) sets out that that subsection applies to the following foods:

(a) a formulated supplementary sports food that does not contain caffeine;
(b) a formulated supplementary sports food that contains caffeine only from any of the following:

    (i) cocoa:
    (ii) chocolate;
    (iii) decaffeinated coffee containing no more than 1 g/kg of anhydrous caffeine on a dry basis;
    (iv) decaffeinated tea containing no more than 4 g/kg of anhydrous caffeine on a dry basis;
    (v) decaffeinated instant coffee containing no more than 3 g/kg of anhydrous caffeine on a dry basis;
    (vi) decaffeinated instant tea containing no more than 3 g/kg of anhydrous

caffeine on a dry basis.

The effect of new subsection 2.9.4—4(3) is that the warning statement required under amended subparagraph 2.9.4—4(1)(a)(iii) (see **item [14]** above) only applies to a formulated supplementary sports food that is listed in new subsection 2.9.4—4(3) (see above).

New subsection 2.9.4—4(4) sets out that that subsection applies to a formulated supplementary sports food that contains caffeine other than caffeine from any of the following:

(a) cocoa:
(b) chocolate;
(c) decaffeinated coffee containing no more than 1 g/kg of anhydrous caffeine on a dry basis;
(d) decaffeinated tea containing no more than 4 g/kg of anhydrous caffeine on a dry basis;
(e) decaffeinated instant coffee containing no more than 3 g/kg of anhydrous caffeine on a dry basis;
(f) decaffeinated instant tea containing no more than 3 g/kg of anhydrous caffeine on a dry basis.

The effect of new subsection 2.9.4—4(4) is that the advisory statement and warning statement required under amended subparagraph 2.9.4—4(1)(a)(iv) (see **item [14]** above) only applies to a formulated supplementary sports food that contains caffeine other than caffeine from any of the sources listed in new subsection 2.9.4—4(4) (see above).

Item [16] amends Standard 2.9.4 by adding new sections 2.9.4—11 and 2.9.4—12 after section 2.9.4—10.

New section 2.9.4—11 sets out nutrition information panel requirements specifically for formulated supplementary sports food that contain caffeine other than caffeine only from any of the following:

- cocoa:
- chocolate;
- decaffeinated coffee containing no more than 1 g/kg of anhydrous caffeine on a dry basis;
- decaffeinated tea containing no more than 4 g/kg of anhydrous caffeine on a dry basis;
- decaffeinated instant coffee containing no more than 3 g/kg of anhydrous caffeine on a dry basis;
- decaffeinated instant tea containing no more than 3 g/kg of anhydrous caffeine on a dry basis.

New subsection 2.9.4—11(1) sets out that section 2.9.4—11 applies to a formulated supplementary sports food that contains caffeine, subject to subsection (2).

New subsection 2.9.4—11(2) sets out that section 2.9.4—11 does not apply to a formulated supplementary sports food that contains caffeine only from any of the following:

(a) cocoa:
(b) chocolate;
(c) decaffeinated coffee containing no more than 1 g/kg of anhydrous caffeine on a dry basis;

(d) decaffeinated tea containing no more than 4 g/kg of anhydrous caffeine on a dry basis;
(e) decaffeinated instant coffee containing no more than 3 g/kg of anhydrous caffeine on a dry basis;
(f) decaffeinated instant tea containing no more than 3 g/kg of anhydrous caffeine on a dry basis.

New subsection 2.9.4—11(3) requires the nutrition information panel for the formulated supplementary sports food to state the *average quantity* of caffeine from any source 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(4) specifies where the information required by new subsection 2.9.4—11(3) must be located in the nutrition information 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.

Biologically active substance is defined in Standard 1.1.2 of the Code.

Subsections 1.1.1—10(8) and 1.1.1—10(9) of the Code requires a food for sale – including formulated supplementary sports food – to comply with relevant labelling and information requirements set by the Code, which apply to the sale of food.

Consequently, the effect of new section 2.9.4—11 is that:

- the nutrition information panel for a formulated supplementary sports food containing caffeine other than caffeine from the foods listed in new subsection 2.9.4—11(2) has to state the *average quantity* of caffeine in:
  - a *serving* of the food; and
  - a *unit quantity* of the food; and
- the above information has 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.

New section 2.9.4—12 sets packaging, labelling and information requirements for formulated supplementary sports food that contain caffeine in a multipack comprising of separate individual portions.

Subsections 1.1.1—10(8), (9) and (10) of the Code respectively require a food for sale – including formulated supplementary sports food – to comply with relevant labelling, information and packaging requirements set by the Code, which apply to the sale of food.

New subsection 2.9.4—12(1) provides that the new subsection applies to formulated

supplementary sports food that meet each of the following criteria:

(a) The formulated supplementary sports food contains more than 200 mg caffeine in total, from any source.
(b) The formulated supplementary sports food is sold in packaging that includes individual portions of the food.
(c) Any one of those of individual portions meet each of the following criteria:

    (i) The individual portion is in a solid or semi-solid form (excluding powders)
    (ii) The individual portion is not designed for individual sale.
    (iii) The individual portion does not require further preparation before consumption.

The following example of individual portions of formulated supplementary sports food is provided after subsection 2.9.4—12(1): 'A formulated supplementary sports food sold in the form of bars, chewables or dissolvable strips'.

New subsection 2.9.4—12(2) sets out that section 2.9.4—12 does not apply to a formulated supplementary sports food that contains caffeine only from any of the following:

(a) cocoa:
(b) chocolate;
(c) decaffeinated coffee containing no more than 1 g/kg of anhydrous caffeine on a dry basis;
(d) decaffeinated tea containing no more than 4 g/kg of anhydrous caffeine on a dry basis;
(e) decaffeinated instant coffee containing no more than 3 g/kg of anhydrous caffeine on a dry basis;
(f) decaffeinated instant tea containing no more than 3 g/kg of anhydrous caffeine on a dry basis.

New subsection 2.9.4—12(3) requires a label on the outer package of the formulated supplementary sports food to contain an advisory statement to the effect that the food contains caffeine. This is the advisory statement required by sub-subparagraph 2.9.4—4(1)(a)(iv)(A).

Under subsection 1.2.1—6(2), if the food for sale has more than one layer of packaging and subsection 1.2.1—6(1) requires it to *bear a label*, only one label is required. New subsection 2.9.4—12(3) is therefore needed so that an advisory statement to the effect that the food contains caffeine is required both on:

the outer package of the multipack of the formulated supplementary sports food, and
each inner individual portion as required under new subsection 2.9.4—12(6) (see below).

Bear a label is defined in Standard 1.1.2 of the Code.

New subsections 2.9.4—12(4) to (7) set requirements for each individual portion that is included in the multipack of the formulated supplementary sports food to which new section 2.9.4—12 applies.

New subsection 2.9.4—12(4) requires each individual portion to be separately packaged.

New subsection 2.9.4—12(5) provides that each individual portion must not contain more than 200 mg caffeine in total, from any source.

New subsection 2.9.4—12(6) requires each individual portion – if it has a surface area of 30

cm^2 or greater – to *bear a label* with an advisory statement to the effect that the food contains caffeine.

Bear a label is defined in Standard 1.1.2 of the Code.

New subsection 2.9.4—12(7) defines each individual portion to mean an individual portion that meets the criteria set out in paragraph 2.9.4—12(1)(c).

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

Standard 2.10.4 – Miscellaneous standards for other foods

Items [17] and **[18]** of the Schedule to the variation amend Standard 2.10.4 of the Code.

Standard 2.10.4 sets out certain requirements for food sold as coffee, tea, chocolate, cocoa, gelatine and peanut butter.

Item [17] amends section 2.10.4—2.

Section 2.10.4—2 sets out copies of definitions of terms used in Standard 2.10.4 of the Code.

The amendment inserts a copy of the definition of *high caffeine coffee beverage* set out in subsection 1.1.2—2(3) (see **item [7]** above).

Item [18] inserts a new section 2.10.4—3A into Standard 2.10.4, which sets out labelling requirements for *high caffeine coffee beverages*.

In particular, new section 2.10.4—3A sets out – for the purposes of the labelling provisions in Standard 1.2.1 – the declarations and advisory statements required for a *high caffeine coffee beverage*.

New subsection 2.10.4—3A(1) provides that the declaration of average quantity required by new subparagraph 1.2.1—8(1)(za)(i) is a declaration in the *nutrition information panel* of the *average quantity* of caffeine, from any source, expressed in milligrams, in:

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

Average quantity, *nutrition information panel* and *unit quantity* are defined in Standard 1.1.2 of the Code.

New subsection 2.10.4—3A(2) provides that, for the labelling provisions in Standard 1.2.1, the advisory statements required by new subparagraph 1.2.1—8(1)(za)(ii) are statements to the effect that the food is high in caffeine and that the food is not suitable for children under 15 years of age, or pregnant or breastfeeding women.'

The effect of the amendments in **items [17]** and **[18]** are that where food is a *high caffeine coffee beverage* – that food is required to bear a label that provides the average quantity of caffeine in the nutrition information panel in accordance with Standards 1.2.1 and 2.10.4.

The intent of these amendments is to provide consumers of *high caffeine coffee beverages* with information about the amount of caffeine in these products and advise those consumers that the beverage contains caffeine at a level that is not suitable for children under 15 years

of age, nor pregnant or breastfeeding women. This is consistent with the P1056 assessment indicating that such measures are a risk-proportionate approach to mitigate the risk of inadvertent overconsumption of caffeine via high caffeine coffee beverages, particularly for sensitive subpopulations.

Attachment C – Draft variations to the *Australia New Zealand Food Standards Code* (2nd call for submissions)

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

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 D – Draft variations to the Australia New Zealand Food Standards Code (consultation paper)

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

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—a prescribed caffeine product.

[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 from any source.

Example A food for retail sale that contains caffeine as an ingredient or component as a result of the addition of pure caffeine or of guarana extract.

[3] After subsection 1.1.1—10(7)

Insert:

Example Caffeine present in a food for sale, or in an ingredient of a food for sale, only as a result of the addition of cocoa, chocolate, coffee or tea; is caffeine that is in the food for sale or the ingredient by natural occurrence. The caffeine occurs naturally in the cocoa, chocolate, coffee or tea. Caffeine in a food for sale, or in an ingredient of a food for sale, as a result of the addition of pure caffeine; is not in the food for sale or the ingredient by natural occurrence.

(7A) Subsection (7) does not apply to guarana extract.

Standard 1.1.2 Definitions used throughout the Code

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

Repeal the paragraph, substitute:

(e) subparagraphs 2.9.4—4(1)(a)(iii), 2.9.4—4(1)(a)(iv)(B) or 2.9.4—4(1)(a)(v) (warning statements for formulated supplementary sports food).

[5] Subsection 1.1.2—2(3)

Insert:

prescribed caffeine product means any of the following:

(a) 1,3,7-trimethylxanthine;

(b) guarana extract.

[6] Subsection 1.1.2—3(2)

Insert:

high caffeine coffee beverage means a food for retail sale that:

(a) is a beverage; and

(b) is in a package; and

(c) *bears a label with a *nutrition information panel

(d) contains coffee; and

(e) contains no less than 200 mg caffeine per serving; and

(f) is not one of the following:

(i) a formulated caffeinated beverage;

(ii) a formulated supplementary sports food.

Standard 1.2.1 Requirements to have labels or otherwise provide information

[7] Paragraph 1.2.1—8(1)(za)

Repeal the paragraph, substitute:

(za) for *prescribed beverages—an energy statement (see section 2.7.1—4A);

(zb) for high caffeine coffee beverages:

(i) declarations of *average quantities (see subsection 2.10.4—3A(1)); and

(ii) any advisory statements (see subsection 2.10.4—3A(2)).

[8] Subsection 1.2.1—8(3)

Repeal the subsection, substitute:

(3) For subsection 1.2.1—6(3), the information is:

(a) *warning statements and declarations in accordance with sections 1.2.3—3 and 1.2.3—4; and

(b) advisory statements in accordance with subsection 2.10.4—3A(2).

Standard 1.5.1 Novel foods

[9] At the end of section 1.5.1—3

Add:

(3) Despite any other provision of this Code, a food for retail sale must not consist of, or have as an ingredient or component, caffeine from a novel food unless:

(a) the novel food is listed in the table to section S25—2; and

(b) any conditions of use specified in the corresponding row of that table are complied with.

Standard 2.9.4 Formulated supplementary sports foods

[10] Section 2.9.4—2 Definitions (after the section title)

Insert:

In subparagraphs 2.9.4—4(1)(a)(iii) and (iv) and subsection 2.9.4—11(1), ***caffeine*** does not include caffeine from any of the following:

(a) cocoa:

(b) chocolate;

(c) decaffeinated coffee containing no more than 1 g/kg of anhydrous caffeine on a dry basis;

(d) decaffeinated tea containing no more than 4 g/kg of anhydrous caffeine on a

dry basis;

(e) decaffeinated instant coffee containing no more than 3 g/kg of anhydrous caffeine on a dry basis;

(f) decaffeinated instant tea containing no more than 3 g/kg of anhydrous caffeine on a dry basis.

[11] 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.

[12] 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.

[13] At the end of section 2.9.4—3

Add:

(3) Subject to paragraph 2.9.4—3(2)(c), formulated supplementary sports food must not contain caffeine in total, from any source, at a concentration of:

(a) 5% or more—if the food is in a powdered form; and

(b) 1% or more—if the food is in a liquid form.

[14] 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

Note Section 2.9.4—2 defines caffeine for the purposes of this subparagraph.

(iv) if the food contains caffeine:

(A) an advisory statement to the effect that the food contains caffeine; and

(B) 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

Note Section 2.9.4—2 defines caffeine for the purposes of this subparagraph.

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

[15] After section 2.9.4—10

Add:

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

(1) This section applies to a formulated supplementary sports food that contains caffeine.

Note Section 2.9.4—2 defines caffeine for the purposes of this subsection.

(2) The nutrition information panel for formulated supplementary sports food must state the *average quantity of caffeine from any source in:

(a) a serving of the food; and

(b) a *unit quantity of the food.

(3) The information required in subsection (2) 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 in a multi-pack

(1) This section applies to 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 bars, chewables or dissolvable strips

(2) The advisory statement required by subparagraph 2.9.4—4(1)(a)(iv)(A) must be on a label on the outer package of the formulated supplementary sports food.

(3) Each individual portion must be separately packaged.

(4) Each individual portion must not contain more than 200 mg caffeine in total, from any source.

(5) Each individual portion with a surface area of 30 cm^2 or greater must *bear a label, with an advisory statement to the effect that the food contains caffeine.

(6) In this section, ***each individual portion*** means an individual portion referred to in paragraph (1)(c).

Standard 2.10.4 Miscellaneous standards for other foods

[16] Note to section 2.10.4—2

Insert:

high caffeine coffee beverage means a food for retail sale that:

(a) is a beverage; and

(b) is in a package; and

(c) *bears a label with a *nutrition information panel; and

(d) contains coffee; and

(e) contains no less than 200 mg caffeine per serving; and

(f) is not one of the following:

(i) a formulated caffeinated beverage;

(ii) a formulated supplementary sports food.

[17] After section 2.10.4—3

Add:

2.10.4—3A Labelling requirements—high caffeine coffee beverages

Required declarations

(1) For the labelling provisions, the required declaration of *average quantity is a declaration in the *nutrition information panel of the average quantity of caffeine, expressed in milligrams, in:

(a) a serving of the food; and

(b) a *unit quantity of the food.

Note The labelling provisions are set out in Standard 1.2.1.

Required

(2) For the labelling provisions, the required advisory statements are statements to the effect that:

(a) the food is high in caffeine; and

(b) the food is not suitable for:

(i) children under 15 years of age; or

(ii) pregnant or breastfeeding women.

Note The labelling provisions are set out in Standard 1.2.1.

Appendix 1: FSANZ response to issues raised in submissions to the 2nd CFS

Note: Issues in column 1 of Tables 2 and 3 below have been grouped according to subject. Column 2 of those tables 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: List of submitters to the 2nd CFS

Submitter	Abbreviation
Australian Beverages Council Limited	ABCL
Australian Sports Nutrition	ASN
Complimentary Medicines Australia	CMA
The George Institute	TGI
Healthcare Product Specialists	HPS
NSW Poisons Information Centre	NSWPIC
NSW Food Authority	NSWFA
New Zealand Beverage Council	NZBC
New Zealand Food and Grocery Council	NZFGC
New Zealand Food Safety	NZFS
Australian Food and Grocery Council	AFGC
Australian Institute of Sport	AIS
Elaine Rush, Auckland University of Technology	AUT
Department of Agriculture, Fisheries and Forestry	DAFF
Edith Cowan University	ECU
Individual Submitter 1	IS1
Dietitians New Zealand Sports Special Interest Grp	DNZ
Nutrition Warehouse	NWH
Pharmacare Laboratories	PL
Queensland Health	QLDH
South Australia Health	SAH
Department of Health Western Australia	DoHWA
Therapeutic Goods Administration	TGA

Table 2: Summary of issues concerning the draft variation proposed at the 2nd CFS

Issue raised	Submitter(s)	FSANZ response
Prohibition on: • **the retail sale of caffeine as a food, unless expressly permitted by the Code and** • **a food for retail sale from containing caffeine as an ingredient or component, unless expressly permitted by the Code** *At the 2nd CFS, the draft variation proposed to include caffeine in subsection 1.1.1—10(5) and 1.1.1—10(6), with the effect that food for retail sale must not be caffeine or include caffeine as an ingredient or component—unless expressly permitted by the Code.*		
Stated support for the draft variation.	AFGC DAFF AIS DNZ QLDH SAH	FSANZ notes this support.
Clarification requested in the drafting on the definition of 'highly concentrated caffeine' when derived from a plant source. This is because it is not clear at what point coffee or tea extracts are considered 'highly concentrated' and thus prohibited from being added to food.	CMA	FSANZ considered this issue and subsequently proposed revisions to the draft variation after the 2nd CFS. FSANZ's proposed revisions were released in a consultation paper for public comment in October 2025 (FSANZ, 2025b)). FSANZ responded to this submitter's comment in that consultation paper at Table 3 (p20). See also, sections 2.3.2 and 2.3.3 of this report.
Herbal extracts, flavours or proprietary mixes may contribute low levels of caffeine, when used in a mixed food, submitter suggests that prohibition on caffeine in food only applies when the caffeine level in the final food is above 10 mg per serve.	CMA	FSANZ considered the issue and FSANZ has responded to this submitter's comment in the consultation paper mentioned in the above response (Table 3 (p20)) After considering submissions received, FSANZ decided not to change its position on this issue because: • The prohibition would not apply to or prohibit caffeine that is in the food for retail sale, or in an ingredient of a food for retail sale, by natural occurrence.

Issue raised	Submitter(s)	FSANZ response
		• In relation to the examples provided, the only food additive (flavour) containing caffeine Code permission is for kola beverages. Herbal extracts containing caffeine may be subject to the novel food provisions of the Code.
The blanket exemption provided by subsection 1.1.1—10(7) to substances listed in 1.1.1—10(6) provides an unintended gap that has the potential to permit pre-packaged, ready-to-drink, individual serve products to exceed the 200 mg caffeine limit proposed for FSSF. Notes there are several iced coffee products on the market that contain over 250 mg – 300 mg caffeine per serve that intentionally label as 'naturally occurring caffeine'. Also raised that coffee concentrate which contains approximately 10 shots of 120 mg of caffeine per 500 mL bottle (1200 mg caffeine per bottle) is currently available with no warnings on the packaging (QLDH comment only). Suggest an additional subclause to 1.1.1—10(7) restricting naturally occurring caffeine to a maximum of 200 mg for all foods, where the food is sold as a pre-packaged, ready-to-consume, single serve item.	NSWFA QLDH	FSANZ considered this issue and subsequently proposed revisions to the draft variation after the 2nd CFS. FSANZ's proposed revisions were released in a consultation paper for public comment in October 2025 (FSANZ, 2025b)). FSANZ responded to this submitter's comment in Table 4 (p24). FSANZ does not consider setting a compositional limit for foods for retail sale containing caffeine, regardless of the source, appropriate for the reasons set out in section 2.2.3.1 of the consultation paper. See section 2.3.5 of this report for FSANZ's final decision on this issue.
There is a lack of information requirements on caffeine content in general foods containing naturally occurring caffeine. It is a challenge for consumers to understand and monitor their acute and chronic caffeine intake. Propose that caffeine in general foods for sale that are sold as pre-packaged, ready-to-consume single serve products should be supported by labelling regulations as for FCBs and FSSF. Also recommends: Mandatory advisory statement of 'Contains caffeine', regardless of the source. Mandatory advisory statement that the food is not recommended for children, pregnant or lactating women or individuals sensitive to caffeine beyond 100 mg per serve (i.e. beyond the level in a single cup of coffee).	NSWFA	FSANZ considered this issue and subsequently proposed revisions to the draft variation after the 2nd CFS. FSANZ's proposed revisions were released in a consultation paper for public comment in October 2025 (FSANZ, 2025b)). FSANZ responded to this submitter's comment in Table 4 (p25). The draft variation will set new labelling requirements for coffee-containing beverages with 200 mg or more caffeine per serving. The new section will set out labelling requirements including (a) declaration in the NIP of the average quantity of caffeine and (b) advisory statements to the effect that the food is high in caffeine and not suitable for children under 15 years of age, or pregnant or breastfeeding women. See section 2.3.5 of this report for FSANZ's final decision.

Issue raised	Submitter(s)	FSANZ response
On-label declaration on caffeine content information per serve for packaged foods containing naturally occurring caffeine beyond 100 mg per serve that do not present as FCB or FSSF. Extension of the proposed maximum 200 mg one-day quantity (or per serve) to all foods for retail sale containing caffeine, regardless of the source where that food is sold pre-packaged, ready-to-consume.		
Supports consideration of informing consumers about the amount of caffeine in prepackaged ready to drink coffee products, such as canned iced coffee, when the caffeine is only from naturally occurring sources. While they agree consumers would generally recognise they are consuming caffeine from these products, they have no control over, or knowledge of, how much caffeine is present. This contrasts with coffee made to order where the number of shots can be requested, giving the consumer an indication of the caffeine content of the drink they receive.	NZFS	FSANZ considered this issue and subsequently proposed revisions to the draft variation after the 2nd CFS. FSANZ's proposed revisions were released in a consultation paper for public comment in October 2025 (FSANZ, 2025b)). FSANZ responded to this submitter's comment in Table 4 (p25). See section 2.3.5 of this report for FSANZ's final decision.
Requested the inclusion of a definition of caffeine in the draft variation which specifies the sources of caffeine in instances where caffeine is permitted as an ingredient. Requested a statement in the Code similar to that written in the P1056 2nd CFS: 'although caffeine derived from a plant or plant extract may be an acceptable source, it could still require assessment as a novel food if there are safety concerns related to the plant component or substance'. This would create transparency and easier interpretation. This would create transparency and easier interpretation.	PL	FSANZ considered this issue and has responded to it in a consultation paper for public comment in October 2025 (FSANZ, 2025b)). FSANZ responded to this submitter's comment in Table 2 of the consultation paper (p16). After consideration of submissions to the consultation paper, FSANZ does not consider a definition of caffeine specifying permitted sources of caffeine is warranted. Instead, the draft variation will clarify that this relates to caffeine 'from all sources', including from the addition of pure caffeine or guarana extract (as defined). The draft variation will also clarify a food for retail sale must not consist of, or have as an ingredient or component, caffeine from a novel food unless that novel food is listed in the Code. See section 2.3.2 of this report for further discussion.
The variation should also regulate the retail sale of caffeine (of various concentrations), extracts and concentrates very high in	QLDH	FSANZ considered this issue and subsequently proposed revisions to the draft variation after the 2nd CFS. FSANZ's

Issue raised	Submitter(s)	FSANZ response
caffeine (both liquids and powders), and proprietary blends that contain high concentrations of caffeine, because these could otherwise be considered 'foods' and permitted by the Code. Removing the P1054 variation will leave these extracts unregulated. Examples provided included guarana extract sold as such, and another product containing 22% caffeine. The submitter clarified that they are not referring to traditional coffee extracts such as coffee and tea beverages.		proposed revisions were released in a consultation paper for public comment in October 2025 (FSANZ, 2025b)). FSANZ responded to this submitter's comment in Table 2 (p13). After consideration of submissions to the consultation paper, FSANZ has amended the draft variation to clarify that the retail sale of caffeine (1,3,7-trimethylxanthine) and guarana extract containing caffeine at a concentration of: 5% or more if the product is in a solid or semi-solid form; or 1% or more if the product is in a liquid is prohibited. A guarana extract with a caffeine concentration of 22% sold as a food for retail sale will not be compliant with the provisions in the approved draft variation. See section 2.3.1 and 2.3.2 of this report for further discussion.
The proposed approach does not provide regulatory clarity about whether caffeine-containing plant extracts may be added to food without express permission. Therefore, the proposed approach may not effectually prevent the sale of highly concentrated caffeinated products when the source of the caffeine is from a plant or plant extract. Caffeine-containing plant extracts are not clearly captured by the proposed drafting in 1.1.1—10(5)(g) and (6)(k). Additionally, caffeine in some plant extracts may be considered as present "by natural occurrence", meaning that the proposed prohibition of caffeine would not apply (Std 1.1.1—10(7)). Caffeine-containing plant extracts could be highly concentrated sources of caffeine. The novel foods provision will reliably prevent the sale of all foods containing highly concentrated caffeine from all plant extracts. Their view is that the regulatory approach for caffeine permissions should not rely solely on the novel food provisions as a means to prevent the sale of foods containing plant-sourced highly concentrated caffeine. For example, guarana extract has a history of use in Australia and New Zealand as a component of formulated caffeinated beverages.	NZFS	FSANZ considered this issue and subsequently proposed revisions to the draft variation after the 2nd CFS. FSANZ's proposed revisions were released in a consultation paper for public comment in October 2025 (FSANZ, 2025b)). FSANZ responded to this submitter's comment in Table 2 (p14) of the consultation paper. Guarana extract was the primary extract identified by FSANZ that could be a highly concentrated source of caffeine. FSANZ maintains that for other caffeine containing plant extracts, the use of these extracts will be subject to the prohibition and those that are novel foods for the purpose of the Code would require pre-market assessment. See sections 2.3.1 and 2.3.2 on FSANZ's discussion on guarana extract. The issue relating to natural occurrence is addressed in Table 3 (p20) of the consultation paper. FSANZ has since considered the submissions to the consultation paper relating to guarana extract and caffeine by natural occurrence and has made several amendments to the draft variation to clearly prohibit the sale and addition to food of highly concentrated guarana. See Items [1], [2], [3] and 5] of the

Issue raised	Submitter(s)	FSANZ response
Among the caffeine-containing plant extracts that could be novel foods, their categorisation as novel food could depend on the composition or method of production of the extract (some methods of producing guarana extract use a process similar to that used for instant coffee, and so these guarana extracts could also be considered to contain caffeine 'by natural occurrence'). This means that for enforcement purposes, some extracts may need to be assessed on a case-by-case basis to determine whether they are novel foods. We acknowledge that designating particular plants or plant extracts as novel or otherwise is out of scope, but because the novel food provisions are presented as a means to control the use of caffeine-containing plants or plant extracts, we consider it relevant to highlight examples of plants or plant extracts which are not clearly defined as novel foods.		approved draft variation.
Remove the existing prohibition in paragraph 1.1.1—10(5)(g) *At the 2nd CFS, the draft variation proposed to remove paragraph 1.1.1—10(5)(g) which prohibited 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*		
The 1 and 5% limits introduced by P1054 adequately addressed the risk of acute toxicity thus no other regulation is needed.	ASN	FSANZ's rationale for the removal of the existing prohibition in paragraph 1.1.1—10(5)(g) is at section 2.3.4 of this report. After considerations of all submissions to the 1st and 2nd CFS as well as the consultation paper, alongside the P1056 risk assessment, FSANZ considers the chronic and acute risks associated with consumption of caffeine are sufficient to justify the additional measures proposed (see section 2.2 of this report).

Issue raised	Submitter(s)	FSANZ response
The removal of the 1 and 5% will create confusion for brands that use naturally occurring caffeine ingredients. If concentration limits on caffeine in general foods are removed, it will be unclear how a food product containing these ingredients will be regulated and thus how compliance will be met.	HPS	The amendments in the approved draft variation (Attachment A) will provide clarity for naturally occurring caffeine ingredients by doing the following: • Clarifying when guarana extract is not naturally occurring as per the concentration limits set in the definition. • Providing examples to explain what natural occurrence. means • Providing compositional limits in foods in cases where caffeine is permitted (i.e. 200 mg, caffeine permitted, from all sources in FSSF). • Clarifying that in all other foods, caffeine from any source will not be permitted to be added as an ingredient.
The removal of the 1 and 5% in general foods stifles innovation and limits development in the food industry.	HPS	FSANZ considers that the current permissions to add caffeine to cola-type drinks and FCBs as well as the new permission for FSSFs (see section 2.3.6 of this report), will provide manufacturers with several avenues to create products with added caffeine in a way that is safe and suitable. 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.
There must be clear limits on the dose of caffeine available, therefore the prohibition of pure or highly caffeinated products is required. This is because caffeine is a drug and requires regulation, particularly for young people.	AUT	The approved draft variation will set clear limits for caffeine in food and continue to prohibit pure or highly caffeinated products. Further, FSANZ is setting new compositional limits and labelling requirements in FSSF, in line with the findings of FSANZ's risk assessment. This includes a required warning statement for FSSF containing caffeine: *Not suitable for children under 15 years of age or pregnant or breastfeeding women: Should only be used under medical or dietetic supervision.* To reduce the risk to children and caregivers of children from excessive consumption of caffeine through high caffeine coffee

Issue raised	Submitter(s)	FSANZ response
		containing beverages, the approved draft variation also requires new labelling requirements for high caffeine coffee beverages. See section 2.3.5 of the Approval Report for details.
Any future permissions for caffeine in the food supply should be subject to the 1 and 5% concentration limits if permitted.	NSWPIC	See response above. FSANZ notes any future permission in the Code would be subject to a pre-market safety assessment.
Provided data indicating a drop in the number of exposures to caffeine powder reported to the Poison Control Centre in 2023 and 2024. Considered this demonstrated the effectiveness of regulation in minimising exposures and harm from high concentration caffeine products.	NSWPIC	FSANZ notes this comment. FSANZ has identified several risks associated with caffeine in the food supply (see section 2.2 of this report). The proposed regulation aims to further reduce inadvertent, excessive consumption of caffeine and the risks of harm from high concentration caffeine.
Questions the assumption in the CFS that the 1 and 5% would not be required to protect public health and safety. Currently, the 1 and 5% limits apply to all retail foods irrespective of the source of caffeine including products containing naturally occurring caffeine. The proposed amendments (at the 2nd CFS) would remove this and only apply them to FSSF in liquid and powdered form. Evidence of caffeine overconsumption from naturally occurring caffeine (in the 1st CFS) support the need for regulation. Removal of the limits means that the only regulatory control on naturally occurring caffeine is the therapeutic limit. This undermines the outcomes of P1054 and is inconsistent with the Ministerial Policy Guideline on Regulatory Management of Caffeine in the Food Supply that requires FSANZ to consider exposure to caffeine from all dietary sources. Support retention of the 1 and 5% limits.	NSWFA	FSANZ considers the amendments in the draft variation address the submitter's concern regarding the removal of the P1054 limits and naturally occurring caffeine. These amendments include: • the prohibition on the retail sale of caffeine and of guarana extract as a food and corresponding definition (including concentration limits) of guarana extract • clarification that the proposed prohibition on a food for retail sale containing caffeine as an ingredient or component applies and relates to caffeine 'from all sources' • examples in subsection 1.1.1—10(7) of what is caffeine in a food for sale or an ingredient of a food for sale 'by natural occurrence' • new provision in 1.1.1—10(7A), which provides that the natural occurrence exemption in 1.1.1—10(7) does not apply to guarana extract • new labelling requirements for coffee-containing beverages with high levels of caffeine sold for retail sale • 200 mg one-day quantity in FSSF and associated concentration limits in powdered FSSF.

Issue raised	Submitter(s)	FSANZ response
		After consideration of all submissions on this issue, FSANZ considers the above measures are adequate to manage the risk of caffeine in the food supply and that the P1054 amendment is no longer required.
The repeal of the 1 and 5% limits would permit the supply of caffeine-containing foods via the NZ Supplemented Food Standard [NZ SFS] below the therapeutic single serving dose of 600 mg caffeine.	NSWFA	The operation of the NZ SFS and the TTMRA are outside of FSANZ's remit and out of scope for P1056. Sections 1.4.3 and 2.4.1.3 of the 2nd CFS provided a summary of how the proposed amendments may interact with New Zealand standards. NZFS has advised that paragraph 1.1.1—10(5)(g) of the Code applies to supplemented foods in NZ and that NZFS are reviewing the implications of regulatory measures proposed by this Proposal for the caffeine provisions in the NZ SFS FSANZ's rationale for the removal of the P1054 variation is at section 2.3.4 of the Approval Report.
Clarification sought about high caffeine plant sources (and future novel foods), and whether there is a need to include a limit for caffeine concentration in food where the caffeine is naturally occurring. An extract of a plant where caffeine is naturally occurring can be a significant concentration of caffeine, many times more concentrated than in the plant itself. Food where the source of caffeine is naturally occurring does not seem to be adequately addressed in P1056.	DoHWA	See above response to NZFS on highly concentrated sources of caffeine, guarana and plant extracts (p85).
The removal of the 1% and 5% caffeine concentration limits for liquid and solid foods is not supported. Retaining these limits could exist alongside the proposed drafting changes to 1.1.1—10(5) and (6) and would mitigate some of their concerns about caffeine-containing ingredients being added to foods in a way that could exceed the current regulatory limits for caffeine which were set under P1054.	NZFS	See above response to NSWFA (p88 and 89).

Issue raised	Submitter(s)	FSANZ response
A maximum concentration for caffeine does not address the present lack of regulatory clarity on the permissions for caffeine-containing plant extracts, but it would provide a safeguard against the sale of foods containing highly concentrated caffeine from plant sources. With the proposed approach, products which contain caffeine from plant extracts (e.g., guarana added to smoothie bases and ready to-drink alcoholic beverages) would be required to include a "contains caffeine" advisory statement, but no warning statement; and consumers would not be informed about the quantity of caffeine unless the manufacturer voluntarily chose to provide this information and a lack of regulatory clarity would remain.		
New express permission for caffeine in FSSF *At the 2nd CFS, the draft variation proposed to amend section 2.9.4—3 to permit caffeine to be added to a formulated supplementary sports food and that if added, the food must not contain more than 200 mg of caffeine in a one-day quantity.*		
Support the 200 mg one-day quantity of caffeine in FSSF.	PL AFGC ABCL NZBC NSWFA TGI DAFF DNZ SAH DoHWA NZFS	FSANZ notes this support.
Supports the 200 mg one-day quantity of caffeine in FSSF noting that it prioritises risk mitigation from inappropriate use of caffeine while enabling evidence-based doses targeted for athlete consumption. Cited evidence of risks associated with high caffeine supplements or stacking of caffeine products and noted that a maximum daily caffeine dose would assist consumers to make informed decisions about use. Products may require reformulation and compliance	AIS	FSANZ notes this support. FSANZ is investigating the issue of stacking multiple serves or multiple sources of FSSF in one day through Proposal P1010. Preliminary assessment for P1010 has found limited evidence related to the stacking of FSSF. FSANZ has considered the references provided by the submitter and notes that the references do not raise any issues related to the regulatory changes proposed in P1056. FSANZ will continue to consider

Issue raised	Submitter(s)	FSANZ response
assessments would be required.		the issue in Proposal P1010.
Supports the 200 mg one-day quantity of caffeine in FSSF noting that sports performance benefits from caffeine doses higher than 200 mg. The 200 mg limit disadvantages athletes who want to consume at the higher end of the dose range to maximise performance.	NZFGC	FSANZ notes NZFGC's support for the 200 mg one-day quantity of caffeine in FSSF. FSANZ's assessment in the 1st CFS found that caffeine intake in exercising and sports people provided a beneficial ergogenic effect at a range between 1.25 mg/kg bw and 6 mg/kg bw. For a 70 kg adult, this converts to a range of 87.5 – 420 mg caffeine which is consistent with the permission to add 200 mg per one-day quantity to FSSF and allows for reasonable consumption of other foods containing caffeine.
Supports the 200 mg one-day quantity of caffeine in FSSF but states that widespread use of caffeine in sports foods is not an argument to justify the continued addition of caffeine to sports foods. The addition of caffeine to sports foods has been driven by market forces and not government policy or informed by a risk assessment. Also stated there is a risk that the permission provides the means for larger caffeine doses to be legally introduced into other foods such as FCBs. It is thought there are inconsistencies with the approach to caffeine labelling across the varying food categories.	QLDH	FSANZ notes QLDH's support for the 200 mg one-day quantity of caffeine in FSSF. Code permissions for the addition of caffeine to sports foods are approved by Australian and New Zealand food ministers following an independent, evidence-based assessment conducted in accordance with the FSANZ Act. As outlined in the first CFS, FSANZ's assessment concluded that caffeine has a demonstrated ergogenic benefit in sports performance. Setting a maximum one-day quantity of 200 mg provides an appropriate safety margin for consumers and offers regulatory certainty for manufacturers and enforcement agencies. The permission also establishes clear limits for its use in specific sports foods and helps ensure that imported products comply with Code requirements. This permission for sports foods does not affect the permitted amount of caffeine in formulated caffeinated beverages (FCBs), which are regulated under a separate Standard. Specific labelling requirements have been developed for different product types, reflecting their distinct purposes and compositional needs.
It is unclear how the proposed requirements in section 2.9.4—3	QLDH	Capsules, tablets, and pastilles may not be regulated as sports

Issue raised	Submitter(s)	FSANZ response
would apply to FSSF in the form of capsules, tablets and pastilles because it is uncertain if they are solid or semi-solid forms. It is requested that these forms are discussed in the Approval Report.		foods if they meet the requirements of section 7 of the TG Act and therefore are regulated as a therapeutic. See section 1.4.2 of this report. Regulation of sports foods in different forms is broader than whether the sports food contains caffeine. The issue is more appropriately considered in Proposal P1010 which will consider compositional requirements of FSSF.
Advocated for a 400 mg daily caffeine limit, citing its recognition as a safe threshold and greater suitability for athletes seeking performance benefits. The 200 mg limit is claimed to be inconsistent with FSANZ's own risk assessment, which found no adverse effects at 400 mg per day in non-pregnant adults. They recommend permitting up to 400 mg from all sources daily, with a maximum of 200 mg per serve with appropriate labelling, including caffeine content per serving, warnings, dosage guidance and clear advisories against concurrent intake from other caffeine sources.	ASN NWH CMA HPS	The one-day quantity of caffeine in FSSF is limited to 200 mg, as determined by FSANZ's safety assessment. This assessment found that a single acute dose of up to 210 mg and a daily intake of up to 400 mg does not pose adverse effects for the general adult or adolescent populations. However, exceeding these levels may present health risks. The 200 mg limit accounts for overall caffeine consumption from all dietary sources within the Australian and New Zealand populations. While caffeine provides a mild ergogenic benefit at doses between 1.25–3 mg/kg body weight, there is limited evidence supporting enhanced performance at intakes above 3–6 mg/kg. Although multi-serve packets may contain more than 200 mg of caffeine, the maximum permitted one-day intake from FSSF remains capped at 200 mg to mitigate cumulative exposure and associated risks.
Did not support the 200 mg maximum one-day quantity because consumers seeking effective, internationally standard doses (>200 mg) will inevitably turn to direct online imports, which may lack rigorous quality control, accurate labelling, or could contain undeclared or prohibited substances, potentially increasing consumer risk.	ASN NWH	Regulation of e-commerce (online sales) of food is a matter for the Australian and New Zealand food laws that apply the Code. E-commerce is not within the scope of this Proposal. FSANZ notes the policy paper recently published by FRSC for food sold online[19]. A new policy guideline, if implemented, on information that should be provided when a food is sold online will be considered as part of the assessment of the broader proposal P1010 on sports foods.

[19] Australian Government (2025) *Information for Food Sold Online: Understanding and Defining the Problem* **at** Information for Food Sold Online: Understanding and Defining the Problem | Food Regulation

Issue raised	Submitter(s)	FSANZ response
Mandatory warning statement for FSSF containing caffeine *At the 2nd CFS, the draft variation proposed to amend section 2.9.4—4 to include breastfeeding women in the warning statement.*		
Stated they support the draft variation to the mandatory warning statement for FSSF containing caffeine.	AFGC ABCL NZBC NSWFA TGI DAFF DNZ SAH NZFS NZFGC	FSANZ notes this support.
Children under the age of 18 years should be protected from harm of consuming caffeinated FSSFs. Noted that FSANZ states on its website that there is 'no recognised health-based guidance value, such as an Acceptable Daily Intake, for caffeine' and also that the Australian Dietary Guidelines recognises that caffeinated drinks like energy drinks are not suitable for children. Recommends amending the current mandatory warning statement for FSSF to not suitable for children aged under 18 years [i.e. change limit from 15 to 18 years of age].	ECU	The rate of clearance of caffeine in adolescents is comparable to that of adults, so caffeine intake up to 3 mg/kg bw as an acute dose is likely to be safe for this age group. There are only minor/insignificant differences in body weight between adolescents (15-18 years in this context) and adults. A single acute dose of up to 210 mg is therefore not associated with adverse effects in adolescents aged between 15 and 18 years. FSANZ has therefore not changed the age from 15 years to 18 years in the warning statement for FSSF.
Recommended revising the warning statement to include: *The recommended maximum daily limit of caffeine is 200 mg*. (or serving equivalent).	PL	The labelling requirements have not been amended to require a reference to the maximum one-day quantity of caffeine from FSSF. The proposed maximum 200 mg one-day quantity of caffeine 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 adolescents and adults who are not pregnant. It therefore allows for additional consumption of other foods containing caffeine within normal/reasonable levels, without causing a significant risk. The one-day quantity requirement is also relevant when other
Suggested the labelling requirements specify that no more than the one-day quantity should be consumed per day as this is more direct than a statement of the recommended amount and frequency required in subparagraphs 2.9.4—4(1)(b)(i) and (ii) of the Code and is consistent with the labelling requirements for FCBs where there is a required statement in paragraph 2.6.4—5(3)(c) that no more than a one-day quantity should be consumed per day.	NZFS	

Issue raised	Submitter(s)	FSANZ response
		substances are present in the FSSF and is therefore not based solely on caffeine content. Based on those factors and combined with additional risk management measures (advisory statement, warning statement), FSANZ considers the additional wording is not necessary. FSANZ notes that the requirement for FCBs to be labelled with the advisory statement referred to by NZFS is not triggered by the presence of caffeine but is if the FCB contains a 'listed' substance in S28—2 (caffeine is not a 'listed' substance).
Clarification is sought about whether a single serve of FSSF will be required to carry the warning statement to be on the individual package.	DoHWA ECU	For the reasons summarised in this report, the approved draft variation will expressly require the caffeine advisory statement to the effect of 'contains caffeine' to be present on certain individual portions of FSSF. See section 2.3.8.8 of this report. See also Table 6 and sections 2.3.2.1 and 2.3.2.2 of the October 2025 consultation paper (FSANZ, 2025b).
Supported the inclusion of caffeine warning statements for FSSF. To enhance clarity and ensure consistent compliance, recommend changes to combine the advisory statement (to the effect the food contains caffeine) with the warning statement. These aim to clearly distinguish the warning statements between products that contain caffeine and those that do not. E.g. if the food contains caffeine—the warning statement 'The food contains caffeine. Not suitable for children under 15 years of age, or pregnant or breastfeeding women: Should only be used under medical or dietetic supervision'. The current approach – featuring two very similar warning statements – has the potential to cause confusion within the sports food industry. Could result in products containing caffeine being labelled incorrectly and potentially placing consumers (including vulnerable population groups) at risk.	HPS	The warning statement, except for the breastfeeding component, applies more broadly to the FSSF, not just to the caffeine component. FSANZ has therefore not imposed a requirement to co-locate the advisory statement to the effect that the food contains caffeine, with the warning statement. Suppliers may choose however, to co-locate the advisory statement with the warning statement on product labels and this is supported by FSANZ. The approved draft variation clearly identifies and distinguishes between the two different warning statements and which warning statement is required for what. See Attachment A.

Issue raised	Submitter(s)	FSANZ response
The Social Science Literature Review (SD3) found that consumers did not know how to interpret milligrams of caffeine in terms of an effect on health. This evidence affirms the importance of having warning statements for caffeine, in addition to declarations of presence and quantity. Supported including in the warning for FSSF that these products are not suitable for breastfeeding women. However, consider individuals sensitive to caffeine should also be included in the warning. Appreciate the rationale provided (i.e., that the advisory statement 'contains caffeine' is enough to mitigate the risk to those individuals) but note this is inconsistent with requirements for FCBs. Consider the risk to individuals sensitive to caffeine to be similar for these two groups of products and including 'individuals sensitive to caffeine' in the warning for one but not the other could cause consumer confusion.	NZFS	FSANZ notes the support to include breastfeeding women in the warning statement for FSSF. FSANZ acknowledges the wording of the statements for FSSF and FCBs differ, however FSANZ is not aware of any evidence this will result in consumer confusion. FSANZ has maintained the proposed approach, based on the rationale provided in the CFS and as noted by this submitter.
Supported the warning statement for populations such as children, pregnant and lactating women, and caffeine-sensitive individuals and advocates for even more visible and direct warnings for these groups.	NWH	FSANZ notes this support. The warning statement refers to these populations except for caffeine-sensitive individuals, as the 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. It must meet size and legibility requirements, and the wording is prescribed (see section 2.3.8.4 of this report).
Mandatory advisory statement for FSSF containing caffeine *At the 2nd CFS, the draft variation proposed to amend Schedule 9 such 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.*		
Stated their support for the draft variation.	AFGC ABCL NZBC TGI DAFF	FSANZ notes this support.

Issue raised	Submitter(s)	FSANZ response
	DNZ SAH NSWFA NZFS NZFGC	
Although studies suggest advisory statements are not a primary source of information for consumers (with regard to small, bulk packaged items), this may be due to the absence of minimum size requirements (unlike warning statements with a not less than 3 mm in height requirement). Another study indicated consumers desire clearer and more prominent labelling. Prominent and well-worded warning statements for product categories considered high-risk in terms of caffeine exposure—such as FSSF—would be especially critical.	PL	The proposed approach has been maintained, consistent with the existing approach in the Code, whereby advisory statements are not subject to minimum size requirements but are subject to existing requirements to be legible and to be prominent so as to contrast distinctly with the background of the label. A warning statement will also be required on FSSF containing caffeine as outlined in section 2.3.8.4 of this report.
Suggested the wording of the proposed addition to section S9—2 [advisory statement] includes caffeine 'from any source' to align with the wording of proposed paragraph 2.9.4—3(2)(c) and proposed paragraph 2.9.4—12(1)(a), both of which include caffeine from any source.	NZFS	The requirement for this advisory statement is now in subparagraph 2.9.4—4(1)(a)(iv). As FSANZ has now decided to exempt FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee from the requirement to be labelled with an advisory statement (see section 2.3.8.1 of this report), the suggested wording 'from any source' has not been used.
Nutrition information panel requirements *At the 2nd CFS, the draft variation proposed new provisions 2.9.4—11 and 2.9.4—12 to set out nutrition information panel (NIP) requirements for caffeine-containing FSSF.*		
Stated their support to require declaration of caffeine in the NIP of a FSSF containing caffeine.	NZFGC AFGC ABCL NZBC NSWFA DAFF DNZ SAH	FSANZ notes this support.

Issue raised	Submitter(s)	FSANZ response
Supported a required declaration of the amount of caffeine present in a serving and 100 g or mL of a FSSF but suggest this is declared as per the example in Schedule 12 for FCBs, so caffeine would be listed below the heading 'Composition Information'. This would promote consistency and could help consumers more easily find caffeine content across different products.	NZFS	On the label of a FCB, the average quantity of caffeine must be expressed per serving and per 100 mL of the FCB. This declaration must not be in the NIP but may be adjacent to the NIP and may be set out in the format in section S12—5. Given the voluntary nature of where the average quantity of caffeine can be declared on an FCB, using the same format as in section S12—5 for FSSF would not guarantee consistency. The proposed approach is consistent with the format of NIPs in general, whereby other biologically active substances (in addition to the mandatory nutrients) are declared at the bottom of the NIP. The proposed approach has therefore been retained.
General labelling		
Noted that if residual caffeine from sources that naturally contain caffeine are present in FSSF, those products would be required to include label declarations of caffeine from incidental sources despite their negligible risk, and despite no labelling advisories being required for other foods (e.g. dark chocolate, decaf coffee). Propose products containing caffeine at < 10 mg per serve should not be required to declare 'contains caffeine' on the label to avoid unnecessary regulatory burden for products that are unlikely to pose health risks.	CMA	For the reasons summarised in this report, the approved draft variation will exempt FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee from the caffeine-related labelling requirements. See section 2.3.8.1 of this report. See also Table 5 and section 2.3.1.1 of the October 2025 consultation paper (FSANZ, 2025b). FSANZ considers that this approach means a quantifiable caffeine threshold is not necessary.
Note there is no quantifiable caffeine threshold which triggers when a product should include the caffeine warning statements. It is unclear if a FSSF that contains naturally occurring caffeine, e.g. a mocha-chocolate flavoured FSSF powder can contain caffeine without a caffeine warning statement, or if the FSSF product is required to include warning statements per FSANZ amendments. As the legislation currently stands, it appears that any FSSF containing caffeine (from natural sources or synthetic sources) is mandated to be labelled in accordance with the proposed draft variation.	HPS	See above response.

Issue raised	Submitter(s)	FSANZ response
Requests FSANZ to provide clear guidance and clarification for products and recommend a quantifiable level of caffeine which requires a caffeine warning statement on FSSF containing caffeine (either as an added ingredient or naturally occurring). These measures would promote greater consistency, support industry compliance, and enhance consumer safety		
Queries that if subsection 1.1.1—10(7) of the Code allows for the presence of caffeine by natural occurrence in a compliant food or ingredient, would cocoa (which naturally contains caffeine) added to FSSF trigger the requirement to declare caffeine in the NIP. This seems excessive and is out of line with other standards, e.g. chocolate containing cocoa does not trigger labelling requirements.	NZFGC	See above response.
Supported the proposed labelling provisions for caffeine-containing FSSF being applied regardless of the source or amount of caffeine. This means that the caffeine-specific labelling provisions are required for products containing small amounts of caffeine (e.g., when the source is cocoa powder). Agree with FSANZ that the required declaration of caffeine quantity will help prevent consumers being misled when FSSF contains less caffeine than the amount needed for an ergogenic effect, because consumers will be informed about the quantity present.	NZFS	FSANZ notes this support. However, please see responses above. FSANZ has decided to exempt FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee from the labelling requirements.
Label must include all levels of added caffeine and risk warning.	IS1	FSSF containing caffeine (unless the caffeine is only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee) will be required to be labelled with a warning statement and the amount of caffeine present from all sources. See sections 2.3.8.4 and 2.3.8.6 of this report.
Cited evidence of products that were not labelled as containing caffeine or with differing caffeine content to that specified on the label and noted that clear articulation of caffeine dose would assist consumers to make informed decisions about use. Compliance assessments would be required on implementation.	AIS	FSANZ notes this comment.

Issue raised	Submitter(s)	FSANZ response
FSSF in liquid and powdered forms that contain caffeine *At the 2nd CFS, the draft variation proposed a new provision in section 2.9.4—3 that sets out concentration limits for FSSF in powdered form (5%) and liquid form (1%).*		
Support the proposed concentration requirements for FSSF in powdered and liquid form of 5% and 1% respectively.	AFGC ABCL NZBC TGI NSWPIC DNZ SAH DoHWA NZFS DAFF	FSANZ notes this support.
The drafting is not clear that the 5% and 1% limits in powdered and liquid FSSF refers to caffeine from any source, as only 'caffeine' is referred to in subsection 2.9.4—3(3).	CMA	Subsection 2.9.4—3(3) has been amended to clarify that caffeine refers to caffeine from any source. This amendment clarifies that the concentration limits apply to caffeine from all sources. See section 2.3.7 of this report for further detail.
The upper limits proposed for FSSF should apply to caffeine from all sources to avoid creating an unintended permission which allows a higher concentration of caffeine from naturally occurring extracts. FSANZ should consider changing the proposed amendment of section 2.9.4—3(3) to "Caffeine [insert 'from any source'] must not be present in…."	QLDH	See above response.
Requested clarification regarding the use of the terms solid, semi-solid and powder. The submitter notes that the current paragraph 1.1.1—10(5)(g) refers to solid and semi-solid foods and believes that FSANZ has replaced 'solid' with 'powder' and inadvertently omitted 'semi-solid' in the proposed section 2.9.4—3. Therefore, it is unclear how a sports bar (solid) and sports gel (semi-solid) would be regulated. Recommends that both 'semi solid' and 'solid' product formats be reinstated or clarified under 2.9.4—3(a) to ensure compliance and certainty for brands formulating products in these	HPS	The references in section 2.9.4—3 to 'powder' instead of 'solid' or semi-solid are intentional. P1056 proposes 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 (the maximum limit) is included in paragraph 2.9.4—3(2)(c) of the proposed draft variation and applies to all FSSF containing caffeine.

Issue raised	Submitter(s)	FSANZ response
formats.		However, because of differences in the types of FSSF products the new permission will apply to, different risk management approaches (and corresponding draft variations) have had to be implemented. The intent of the former paragraph1.1.1–10(5)(g) was to restrict the retail sale of pure and concentrated caffeine in all forms – solids and semi-solids (which includes powders), and liquids. The new '5% or more' restriction in paragraph 2.9.4–3(3)(a) is a compositional limit which applies only to FSSF in a powdered form. It is intended to restrict the amount of caffeine in bulk powders which are sold in a container that contains multiple serves (e.g. a pre workout powder in a container containing 30 serves). For solid and semi-solid forms of FSSF, packaging requirements have been employed through section 2.9.4–12. This is intended to restrict the caffeine amount in solid or semi-solid products sold in bulk form (e.g. multiple individual pieces such as gummies in a large 'bulk' packet). A sports bar or a sports gel as cited by the submitter would need to comply with the 200 mg daily limit set in paragraph 2.9.4—3(2)(c). If sold in a multi-pack, then section 2.9.4—12 would also apply.
Whilst supportive of the proposed regulation, a percentage calculation adds a layer of complexity to Imported Food Inspection Scheme (IFIS) assessments.	DAFF	Paragraph 1.1.1—10(5)(g) of the Code currently sets concentration limits for caffeine in solid, semi-solid or liquid form that require a percentage calculation. The approved draft variation will remove this general requirement and apply these concentration limits to specific FSSF (those in powder and liquid form) only, thus minimising the number of different products that require a percentage calculation. FSANZ notes that percentage measurement and limits are used throughout the Code and is not aware of any issues with their use.

Issue raised	Submitter(s)	FSANZ response
Packaging of solid or semi-solid caffeine-containing FSSF in a multi-pack *At the 2nd CFS, the draft variation proposed a new provision in section 2.9.4—12 that sets out a packaging requirement for FSSF that contains caffeine and comprises of separate portions.*		
Support the packaging requirements for separate portions of FSSF that contain caffeine.	AFGC ABCL NZBC TGI DNZ SAH DoHWA	FSANZ notes this support.
Does not support removal of the 5% caffeine concentration limit for non-powdered solid and semi-solid small volume FSSF as they do not agree that a product containing more than 5% caffeine should be permitted as an FSSF if it provides no other nutritional purpose. These products should be regulated as therapeutic goods. Sought further information to justify the proposed approach, in that a separate packaging requirement provides sufficient risk management for products containing more than 5% caffeine and more than 200 mg caffeine in a whole product to be sold as FSSF.	NSWFA	As noted above, section 2.9.4–3 permits any FSSF to contain caffeine up to a maximum one-day quantity. However, because of differences in the types of FSSF products the new permission will apply to, different risk management approaches have necessarily been proposed. The intent of the paragraph 1.1.1–10(5)(g) is to restrict the sale of concentrated caffeine in all forms – solids and semi-solids (which includes powders), and liquids. The new '5% or more' restriction in paragraph 2.9.4–3(3)(a) is a compositional limit which applies only to FSSF in a powdered form. It is intended to restrict the amount of caffeine in bulk powders which are sold in a container that contains multiple serves (e.g. a preworkout powder in a container containing 30 serves). For non-powdered solid and semi-solid small volume products, the 5% concentration restriction would prevent addition of caffeine to some small volume FSSF products with a legitimate sports nutrition purpose. Therefore, individual packaging requirements for these types of products, as specified in section 2.9.4—12, was determined to be an appropriate risk management approach. See section 2.3.7 of this report and section 2.2.4 of the 2nd CFS for further information. Regulation of small volume, solid or semi-solid FSSF containing substances such as caffeine or other single nutrients, but no

Issue raised	Submitter(s)	FSANZ response
		other nutritional attributes is a broader issue than proposal P1056. Therefore, the issue is more appropriately assessed in proposal P1010. This includes consideration of both compositional and labelling requirements in a tiered regulatory framework. See P1010 Consultation Paper 1 (FSANZ, 2023).
Raised issues regarding the effectiveness of individual packaging as a risk mitigation strategy, doubting it will change consumer behaviour or adequately protect vulnerable groups such as children from excessive caffeine consumption.	NSWFA CMA QLDH PL NZFS	Individual packaging is considered just one aspect of a broader risk management strategy. Each portion in a multi-pack must not exceed the 200 mg one-day caffeine limit and must comply with all relevant labelling requirements. The form of individual packaging is not prescribed under subsection 2.9.4—12(2); however, it is recognised that individually packaged small volume, highly caffeinated sports foods present a different risk profile compared to undivided packaging, as the packaging helps limit total caffeine exposure. Amendments to the draft variation proposed at 2nd CFS reinforce that no single individually packaged portion may exceed the permitted one-day caffeine quantity. In addition, FSANZ has revised the proposed draft variation to mandate a caffeine advisory statement on individually packaged portions of FSSF, aiming to help parents and caregivers limit children's access to these products.
Proposed rewording section 2.9.4—12 referencing 'small separate portions' to focus on FSSF sold in multi-serve packages intended for consumption over multiple days, suggesting that the word 'small' is unnecessary. Recommend amending paragraph 2.9.4—12(1)(b) to clarify this point. Additionally, for paragraph 2.9.4—12(1)(c), sought clarification that each individual portion is meant to be consumed in one setting or within a day, and recommends introducing a maximum caffeine limit of 200 mg per portion.	NSWFA	FSANZ has updated the title of section 2.9.4—12 to better reflect the section's intent, changing it from referencing 'small separate portions' to a 'multi-pack' for FSSF containing caffeine. The drafting has been revised to ensure that each individually packaged portion in a multi-pack does not exceed the permitted one-day quantity of caffeine, regardless of the number of serves contained. Additionally, provisions have been clarified for multi-packs that collectively contain more than the one-day maximum quantity of caffeine, ensuring regulatory consistency and consumer safety.
Recommended using the term 'individual portion pack' already present in the Code, in proposed section 2.9.4—12. Notes that if the surface area is 30 cm^2 or greater, the requirement for mandatory	NSWFA	The term 'individual portion pack' refers to individual packages for servings that are intended to be used separately i.e. the definition means that the individual portions are already

Issue raised	Submitter(s)	FSANZ response
allergen declarations on 'individual portion pack' (subsection 1.2.1—6(3)) would also apply.		packaged. Section 2.9.4—12 sets a requirement for an individual portion to be individually packaged. Therefore, the term is not appropriate there. However, regardless of the term used, requirements for mandatory allergen declarations and mandatory royal jelly warning statements will apply to the packaged individual portions in a multi-pack.
The additional packaging requirements proposed for small volume FSSF do not align with Australian Government trends to increase sustainability measures, in particular the 2025 National Packaging Targets. The goal of 100% of Australian packaging being reusable, recyclable or compostable by 2025 cannot be met because there are limitations on placing liquids or semi-solids into such packaging. The packaging requirement in section 2.9.4—12 contradicts the goal of phasing out problematic and unnecessary single-use plastic packaging.	CMA	The individual packaging requirement set out in section 2.9.4—12 is intended to manage a food safety risk. Proposal P1054 identified a lower risk for small volume highly caffeinated sports foods. Therefore, the individual packaging requirement set out in section 2.9.4—12 is a necessary measure to manage an identified food safety risk. Subsection 2.9.4—12(2) does not specify the form of packaging required for individual portions in a multi-pack. Therefore, manufacturers have flexibility to aim to meet the 2025 National Packaging Targets while ensuring safety of consumers.
Requested discussion in the Approval Report about whether the proposed drafting would permit the sale of caffeine-containing chewing gum and caffeine pouches (which sometimes contain other substances such as vitamins, taurine and other energy enhancing components) as FSSF.	QLDH	Whether chewing gum and caffeine pouches would be permitted for sale as FSSF is a compliance and enforcement matter for food regulators. If deemed a FSSF, such products would need to meet the composition and labelling requirements of FSSF including use of the prescribed name. FSANZ notes that chewing gum is regulated under Standard 2.10.3. In addition, new section paragraph 1.1.1—10(6)(k) prohibits any food for retail sale containing caffeine as an ingredient or component unless expressly permitted by the Code.
It is unclear how the proposed requirements in section 2.9.4—12 would apply to FSSF in the form of capsules, tablets and pastilles. Requested these forms are discussed in the Approval Report.	QLDH	If the FSSF is solid or semi-solid, not designed for individual sale and does not require further preparation before consumption it may be regulated under section 2.9.4—12 and require individual packaging if sold in packaging consisting of

Issue raised	Submitter(s)	FSANZ response
		individual portions with more than 200 mg caffeine in total. The TGA has declared under section 7 of the TG Act that certain sports supplements are therapeutic goods for the purposes of that Act (and therefore not a food). The declaration means that sports supplements will be regulated by the TGA as therapeutic goods if they are presented in the medicinal dosage of a pill, tablet or capsule or their ingredients meet the criteria of being higher risk to consumers. See section 1.4.2 of this report for further information.
Sought clarification around the intent of the wording 'more than 200 mg of caffeine in total' in paragraph 2.9.4—12(1)(a). It is unclear if the wording refers to total caffeine content in an individual portion or total caffeine content of the package for sale (multi pack).	HPS	FSANZ considers the application of paragraph 2.9.4—12(1)(a) is clear. Subsection 2.9.4—12(1) sets out which FSSF are subject to the requirements imposed by other subsections in section 2.9.4—12. Paragraph (a) of subsection 2.9.4—12(1) clearly states that the latter apply to a FSSF that 'contains more than 200 mg caffeine in total, from any source'. Section 2.9.4—12 now also requires that a separately packaged individual portion that forms part of the multi-pack must not contain more than the permitted one-day quantity of caffeine. This also makes clear that paragraph 2.9.4—12(1)(a) is referring to the entire contents of the multi-pack. The individual packaging requirement is explained further in section 2.3.7 of this report.
It is unclear why individual small separate portions of powdered FSSF that require preparation before consumption are expressly excluded from Standard 2.9.4—12(2) and states a multi pack product, regardless of preparation or format should comply with the requirement.	HPS	A caffeine concentration limit has been applied to FSSF in powdered form. Subsection 2.9.4—3(2) will provide that a FSSF must not contain, in a one-day quantity (as defined), more than 200 mg caffeine in total, from any source. Subsection 2.9.4—3(3) will provide that, subject to the latter requirement, a FSSF must also not contain caffeine in total, from any source, at a concentration of 5% or more if the FSSF is in a powdered form. This reflects FSANZ's assessment that powders containing less than 5% caffeine concentration are of lower risk as a person

Issue raised	Submitter(s)	FSANZ response
		would have to consume several tablespoons of powder to lead to severe adverse health effects. These conclusions are applicable to FSSF in powdered form. Therefore, FSANZ considered the above to be an appropriate risk management measure. The labelling requirements relevant to FSSF under Standard 2.9.4 will also apply.
Requested FSANZ clearly define the terms 'small separate portions', 'contains more than 200 mg caffeine in total', 'solid or semi-solid form', and 'do not require further preparation before consumption' for consistent regulatory compliance.	HPS	FSANZ has made amendments to the drafting of section 2.9.4–12 to clarify the intent of the individual packaging requirement. These amendments are outlined in section 2.3.7 of this report. The amendments are expected to assist in compliance and enforcement of the requirement by more clearly defining the dependency of product size, form and/or composition.
The example provided in section 2.9.4—12 of the proposed drafting should not refer to dissolvable strips because an example should not be used to provide an indication of whether caffeine-containing dissolvable strips should be regulated as food.	NZFS	Determination of what is regulated as a food (as opposed to a therapeutic) is out of scope for this proposal and will be given further consideration in Proposal P1010. FSANZ has however expanded the example to include bars to better reflect the intent of the example that the requirement does not only apply to dissolvable strips.

Table 3: Other issues and suggestions

Issue	Submitter(s)	FSANZ Response
Stacking		
The proposed risk mitigation of the one-day quantity and labelling statements do not address the risk posed to children and other people stacking with similar or other caffeinated products. Recommends a required warning statement for caffeine-containing FSSF with words to the effect that it is recommended consumers not 'stack' with other sources of caffeine.	ECU	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 proposal does not consider the risks posed by stacking of caffeine-containing products in relation to the proposed permission to add caffeine to sports foods.	DoHWA ECU NWS	See response above.
Links to proposal P1010		
Concerned about the potential for general level health claims (GLHC) to be made on caffeinated food, as FSANZ has determined caffeine to be a 'biologically active substance'. While there are currently restrictions on certain types of claims in the FSSF standard, it is unclear whether GLHC can be made on food containing natural sources of caffeine. Needs future considerations (P1010) of the application of claims to FSSF.	DoHWA	Whether caffeine is deemed to be a biologically active substance or if it is from a natural source does not in itself determine whether a GLHC can be made about a food containing caffeine. GLHCs about a food must comply with the conditions for making such claims in Standard 1.2.7 and S4. Additionally, for FSSF, section 2.9.4–7 prohibits an express or implied representation that relates any property or proposed use of the food to enhanced athletic performance or beneficial physiological effects unless permission is provided for such a claim in Standard 2.9.4. There is no permission in Standard 2.9.4 for a claim about enhanced athletic performance or beneficial physiological effects in relation to caffeine. The regulation of health claims for FSSF will be considered in Proposal P1010 – Formulated Supplementary Sports Foods.
Supports FSANZ view that caffeine is a biologically active substance in FSSF and suggests the existing conditions for nutrition content claims about properties of food not in section S4—3 (section 1.2.7—	NSWFA	Existing conditions in relation to nutrition content and health claims about caffeine in Standard 1.2.7 and Schedule S4 will apply, irrespective of the source of caffeine, as suggested by

Issue	Submitter(s)	FSANZ Response
8) should apply. Also suggested the existing conditions should apply to health claims about caffeine for all foods, regardless of the source. Would like clear identification of caffeine as a 'biologically active substance' when not used as a food additive in the approval report so it is clear for stakeholders. This is because of notified health effects relating to mental performance and weight loss which do not specify the food category the claims are intended to be used for or if the claims are about added or naturally occurring caffeine. The P1056 approach would permit general foods containing naturally occurring caffeine over the levels in FSSF and FCBs and exceeding the safe level of 200 mg for a single serve, to make nutrition content claims and/or health claims about their caffeine content. The prohibition of representation about enhanced athletic performance or beneficial physiological effects in section 2.9.4—7 does not apply to general foods. Recommended considering regulating performance-related claims about naturally occurring caffeine in general foods as part of Proposal P1010. It is unclear in the context of P1010 if 'sports foods' refers to only FSSF or also includes general foods with sports representation. Urges FSANZ to review the regulation on performance-related health claims for all foods (i.e. not limited to FSSF) under Proposal P1010 as there will be a distorted market concerning on-pack claims for caffeine content in general foods compared to FSSF if not considered. Proposal P1010 should consider appropriate/acceptable product representation and marketing practice (including the use of claims, line marketing and stacking) of food containing substances for performance-enhancing purposes, so that the risk of inadvertent overconsumption of psychoactive substances by vulnerable populations is appropriately managed.		NSWFA. FSANZ does not consider that specifically identifying caffeine as a biologically active substance when not used as a food additive would assist with identifying the food category that notified claims are intended to be used for. The definition of biologically active substance in the Code (a substance, other than a nutrient, with which health effects are associated) does not rely on natural occurrence of the substance. Following consideration of submitter comments, FSANZ has decided to include additional measures in relation to naturally occurring caffeine – see sections 2.3.3 and 2.3.5 of this report. The regulation of foods other than FSSF (products specifically formulated to assist sports people in achieving specific nutritional or performance goals) is out of scope of P1010. The regulation of product representation and marketing practices for FSSF as well as the definition of FSSF will be considered in P1010 – Formulated Supplementary Sports Foods.
Supports approval of a general level health claim (GLHC) for the beneficial effects of caffeine on sports performance, based on:	NZFGC AFGC ABCL NZBC	Section 2.9.4—4 expressly prohibits performance claims on FSSF unless permitted. Amendments to this prohibition, if any, are being considered under P1010. This includes the regulatory framework for assessing such performance claims about FSSF.

Issue	Submitter(s)	FSANZ Response
• supporting evidence which has already been assessed under Proposal P1056 • efficient to permit this claim now rather than delay consideration until Proposal P1010 • a pre-approved claim at a defined and safe dosage would provide timely, accurate information to consumers, thereby supporting informed decision-making and promoting consumer safety in relation to caffeinated products.		FSANZ considers permission for health claims about caffeine should be reviewed in the broader context of the P1010 work.
Raised concerns regarding the coexistence of health claims and warning statements about caffeine on product labels. FSANZ has not addressed claims in the proposed variation, emphasising the need to assess whether current warning messages for caffeinated FSSF remain effective in the presence of such claims. The risk is that consumers may overlook critical warnings, such as 'not suited for children', if influenced by positive claims like 'may assist in the development of muscle bulk'. This could lead to misinformed choices and increased exposure to caffeine-related risks.	ECU DoHWA	FSANZ notes that the issue of the coexistence of health claims and warning statements on FSSF is broader than the new caffeine warning statement. FSANZ will consider this issue when the regulatory provisions for FSSF are considered holistically through Proposal P1010.
The Code does not provide clarity on the regulatory status and requirements of analogues and derivatives and requested clarification that this issue will be appropriately considered as part of Proposal P1010.	NSWFA	The regulation of permitted forms of substances other than caffeine added to FSSF, including analogues and derivatives, will be considered in P1010 – Formulated Supplementary Sports Foods. Early consideration has been given to them in the P1010 consultation paper released in 2023 on the Regulatory Framework for Standard 2.9.4.
The definition of FSSF needs consideration – many products on market for weight loss and body builders with claims such as 'ketogenic' and 'fat burning'.	QLDH	The definition of FSSF will be considered in P1010 – Formulated Supplementary Sports Foods.
Supports the proposed advisory statement for caffeine-containing FSSF but proposes that the requirement is applied after finalisation of P1010 so that label changes, which impose a large cost, can be made universally to affected foods.	CMA	The additional labelling requirements for FSSF containing caffeine need to be implemented in association with the new permission. The requirements are designed to manage the risk associated with the presence of caffeine and therefore, to protect health and safety of consumers. There will be a two-year

Issue	Submitter(s)	FSANZ Response
		transition period to allow time for compliance with the new requirements.
Cost and Benefits Analysis		
Recommended a wording change to page 9 of the Cost and Benefit Assessment where it states: *'The proposal will impact all foods that fall into one of the following categories:* • *general foods with added caffeine – except where caffeine is added for a permitted purpose in the Code* • *sports foods with added caffeine'* Recommended rewording of the second point so that FSSF containing caffeine from any source will be impacted.	NSWFA	FSANZ agrees with this suggestion that it reflects the intent of the draft variation. FSANZ has revised the relevant text in the DRIS.
Recommended a wording change to page 9 of the Cost and Benefit Assessment where it states: *'The analysis assumes that the proposed amendments will apply to supplemented foods under the New Zealand Supplemented Food Standard 2016'.* Recommended rewording to reflect the fact that the NZ SFS clarifies that Standard 2.9.4 does not apply to supplemented food, hence the proposed amendment in Standard 2.9.4 in Proposal P1056 would not apply to supplemented food.	NSWFA	The operation of the *New Zealand Supplemented Food Standard 2016* is explained in section 1.4.4 of this report. FSANZ's understanding is section 1.1.1—10 of the Code currently applies to supplemented foods under that New Zealand standard. Section 1.1.1—10 as amended by the approved draft variation will also apply to those supplemented foods.
The regulation specifically disadvantages AU/NZ businesses because: • the regulation primarily penalises compliant local manufacturers and retailers, while overseas online sellers face minimal practical barriers, creating an uneven playing field tilted against domestic industry	ASN	It is not clear that the proposal will result in a disadvantage to Australian and New Zealand businesses. Amendments made by the approved draft variation apply equally to domestically produced products and imported products. Importers/overseas manufacturers must meet the same requirements as domestic manufacturers. For the same reasons the amendments themselves will not result in locally produced products being less competitive when compared to overseas

Issue	Submitter(s)	FSANZ Response
• reduced sales for local manufacturers and retailers due to less competitive products will lead to significant economic harm and likely job losses within Australia and New Zealand.		imported products
Education and consumer campaigns		
Welcomed the opportunity to collaborate with FSANZ on consumer education campaigns to promote safe and informed caffeine consumption.	ABCL NZBC	FSANZ will work with stakeholders to develop materials to assist understanding of the changes. More details on education are provided in section 3.2 of this report.
Recommended FSANZ's education materials clearly explain the transitional arrangements so that stakeholder confusion will be minimised.	NSWFA	See above response.
Emphasised the importance of effective education measures on the appropriate and safe use of caffeine and requested that FSANZ and jurisdictions create and update their education materials accordingly.	NZFGC	See above response.
FSANZ and other regulatory and health bodies should consider actively disseminating information through social media and online channels to increase the visibility of safe caffeine consumption guidelines and reach a wider audience. This submitter welcomed working with FSANZ to do this.	AFGC	See above response.
Emphasised the need for public education campaigns to raise awareness about caffeine risks particularly in FSSF and FCBs.	SAH	See above response.
NZ Supplemented Food Standard		
Raised issues regarding regulatory misalignment between the proposed Code amendments in P1056 (to section 1.1.1–10) and the New Zealand Food (Supplemented Food) Standard (NZ SFS), regarding caffeine in supplemented foods. The NZ SFS currently permits the addition of caffeine for purposes beyond its use as a food additive, provided labelling requirements are met, and does not	NZFGC AFGC ABCL NZBC	The application and operation of the NZ SFS is primarily a matter for the New Zealand Government. FSANZ's understanding of the NZ SFS as it currently applies to supplemented foods was summarised in the 2nd CFS (section 1.4.3). As noted, Section 1.4 of the NZ SFS lists certain standards of the Code that do not apply to supplemented food,

Issue	Submitter(s)	FSANZ Response
specify a maximum permitted caffeine level.		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. NZFS has advised that paragraph 1.1.1—10(5)(g) of the Code applies to supplemented foods in NZ and that NZFS are reviewing the implications of regulatory measures proposed by this proposal for the caffeine provisions in the NZ SFS.
The New Zealand Ministry for Primary Industries (MPI) would need to amend the NZ SFS to ensure the proposed changes to the Code do not apply to supplemented foods and would be making a formal request to MPI to this effect. Urged FSANZ to ensure clarity in this area, especially in the absence of a New Zealand Therapeutic Goods Act to cover such products.	NZFGC	The application, operation and amendment of the NZ SFS is a matter for the New Zealand Government.
It is unclear how the current risk categorisation of food relating to the 1 and 5% concentration limits will be impacted by P1056. There is currently an exemption for products regulating under the NZ SFS from having to comply with Standard 2.9.4 of the Code and currently, if the 1 and 5% concentration limits are removed, what will the impact be, especially where the source of caffeine is naturally occurring.	DoWHA	See responses above regarding the operation of the NZ SFS.
Aware this proposal has implications for caffeine provisions in the NZ SFS, which permits supplemented food to contain caffeine for a purpose other than as a food additive. An advisory statement and nutrition information must be provided on the label if it contains a greater level of caffeine than is required to achieve a technological function under conditions of Good Manufacturing Practice. 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	FSANZ notes this comment.
Novel foods		

Issue	Submitter(s)	FSANZ Response
Common caffeine-containing plant extracts (e.g. guarana and green tea extract) should not be considered novel foods and require pre-market assessment solely due to their caffeine content. These are used globally, are safe and often have GRAS status.	ASN	Whether or not a particular plant source of caffeine is a novel food is not in scope of P1056 (see section 1.4 of the 1st CFS (FSANZ 2022)). FSANZ notes that caffeine-containing plant extracts may require premarket assessment irrespective of their caffeine content. Plant extracts are of variable composition, depending on factors such as the method and degree of extraction, and the final composition of the extract. 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. Guarana extract is a permitted source of caffeine where caffeine is permitted in the Code (i.e. FCBs and FSSF). As noted in the 1st CFS, the US GRAS system is not comparable to the premarket assessment requirements for novel foods in Australia and New Zealand.
Agreed that some caffeine-rich plant extracts may be unapproved novel foods. However, while agreeing with the general prohibition of unapproved novel foods in the Code, requested that FSANZ prioritises the finalisation of Proposal P1024 so stakeholder ambiguity concerning the regulatory status of caffeine rich plant extracts may be resolved.	NSWFA	FSANZ notes this comment.
Formulated caffeinated beverages		
High caffeine energy drinks should not be sold to children under 18 years.	IS1	Formulated caffeinated beverages (‘energy drinks’, or FCBs) are regulated under Standard 2.6.4 and are subject to compositional and labelling requirements. These beverages must contain between 145 mg/L and 320 mg/L caffeine. They must be labelled with advisory statements to the effect that the product contains caffeine and that the product is not recommended for children, pregnant or lactating women or individuals sensitive to

Issue	Submitter(s)	FSANZ Response
		caffeine. FSANZ has not identified a risk that would necessitate amending the requirements for FCBs. This is based on the outcome of FSANZ's safety assessment which had regard to the best available evidence (see section 2.2 of this report) and the existing risk management measures for FCBs.
Proposed that sale of FCBs should be prohibited to people under the age of 18 years in Australia and New Zealand due to the significant negative impact they have on children's health. FSANZ should consider a mandatory warning statement in Standard 2.6.4 of 'not suitable for children aged under 18 years, pregnant or lactating women and individuals sensitive to caffeine'. Several countries have restricted energy drinks to children and provided research on the need to take precautions with energy drink sale and consumption due to health effects associated with energy drink consumption. Provided a summary of their own research relating to energy drink consumption in Western Australian children, factors that drive consumption, adverse effects and perceptions of energy drink safety. Their research also demonstrates that children consider energy drinks are marketed to them.	ECU	See above response.
Noted the restriction of sales of energy drinks to youths 16 years and under (in some retail outlets in New Zealand) and suggested this should be mandated for all sales of energy drinks in all outlets.	AUT	See above response.
Supported FSANZ's position to not change the current permissions under the FCB standard.	NZFGC	FSANZ notes this support.
Other		
Emphasised the need for an updated National Nutrition Survey and for comprehensive, independently collected data on the composition of foods currently available in the Australian market. Their	TGI	FSANZ's assessment had regard to the best available evidence including nutrition survey data. See SD2 for more.

Issue	Submitter(s)	FSANZ Response
FoodSwitch dataset can facilitate useful analysis and support monitoring and enforcement of regulation.		
The risk to children, including adolescents, has not been considered fully with the proposed P1056 approach to ensure alignment with the Ministerial Policy Guideline on the Regulatory Management of Caffeine in the Food Supply and given the Ministers' original request of P1054 for 'information about current permissions in the Code, and preliminary recommendations for strengthening regulations and consumer warnings'.	ECU	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 4.3 of this report). 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 little substantiated evidence that adolescents or children are regularly consuming caffeine in excess of their respective safe recommended limits (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). Also see above responses related to this issue – including that FSANZ is setting new compositional limits and labelling requirements in FSSF, in line with the findings of its risk assessment. This includes a required warning statement for FSSF containing caffeine: *Not suitable for children under 15 years of age or pregnant or breastfeeding women: Should only be used under medical or dietetic supervision.* As stated above, FSANZ has revised the proposed draft variation to mandate a caffeine advisory statement on individually packaged portions of FSSF, which will help parents and caregivers limit children's access to these products. As stated above, to reduce the risk of excessive consumption of caffeine through high caffeine coffee containing beverages, FSANZ is also requiring new labelling requirements for high caffeine coffee beverages. See section 2.3.5 of this report.
Provided data indicating that the number of exposures reported to NSW PIC related to caffeine-containing products, including FSSF,	NSW PIC	FSANZ notes this comment and considers the 200 mg one-day quantity, caffeine concentrations in powders and liquids, and associated labelling requirements for FSSF (see section 2.3.6 of

Issue	Submitter(s)	FSANZ Response
has remained relatively consistent over the past two years, although the proportion of exposures which involve FSSF has increased, from 28% in 2022 to 30% in 2023 to 32% in 2024.		this report for FSANZ's rationale) to appropriately manage the risk of caffeine exposure from FSSF consumption.
Indicated they would need to consult with FSANZ on a review of the imported food risk advice on pure and highly concentrated caffeine products.	DAFF	FSANZ notes this comment.
Recommended that given the potential for increased exposure of children to caffeine and the import pathway enabled by the TTMRA, FSANZ review the evidence to assess whether imported caffeinated foods pose a medium to high public health risk. Also recommends considering the classification of these imported caffeine/caffeinated products as risk foods requiring surveillance under the *Imported Food Control Regulations 1993.*	ECU	See response above in relation to the TTMRA and the NZ SFS. DAFF are responsible for the administration of the *Imported Food Control Regulations 1993*.
Provided information regarding caffeine and caffeine-containing materials used as ingredients in food products and medicines. Noted the following: • Whether a caffeine-containing product is a food or a medicine depends on several factors including ingredients, tradition of use as a food and form, whether there is a food standard, overall presentation and claims. • Certain caffeinated sports supplements are regulated as therapeutic goods. A good will not be a therapeutic good where there is a food standard and unless the food has been declared to be a therapeutic good under an order in force under section 7 of the TG Act. • A good that satisfies the definition of an FSSF under Section 2.9.4—2 in the Code is excluded from the definition of therapeutic goods unless there is an order in force under section 7 of the TG Act that applies. • Caffeine, when contained in goods containing greater than 600 mg of caffeine (as included in Schedule 4 of the Poisons Standard) per daily recommended dose (or greater than 5% caffeine) is a substance included in a schedule to the Poison's	TGA	FSANZ notes this information.

Issue	Submitter(s)	FSANZ Response
Standard. This means that sports supplements containing caffeine beyond this level, which would otherwise be covered by the FSSF standard, are covered by the Declared Goods Order, and consequently are therapeutic goods. • Sports supplements containing caffeine below 600 mg (or less than 5%) are not covered by the Declared Goods Order (unless captured by other provisions or containing other scheduled substances) as the level of caffeine is below the amount set out in the relevant Poisons Standard schedule and if are FSSFs, they are excluded from the definition of therapeutic goods because there is a food standard. • If the proposed approach for P1056 is approved, an FSSF containing less than 600 mg caffeine per daily recommended dose or less than 5% caffeine, and that is not in the dosage form of a tablet, capsule or pill, is not covered by the Declared Goods Order and so will not be a therapeutic good unless it is covered by another provision of the Declared Goods Order or another declaration order. For these products, if they contain over the 200 mg one-day quantity, may be considered to be a good that is not compliant with the Code. • If the proposed prohibition for P1056 is approved, some goods will no longer be compliant with the Code. This does not mean that these goods will necessarily be considered therapeutic goods. Goods that have a tradition of use as a food in Australia or New Zealand or which have a standard that applies are excluded from the definition of therapeutic goods under the TG Act. Further, goods (such as caffeine pouches) which do not have a tradition of use as a good, but do not make therapeutic claims for the product, may also not be considered therapeutic goods.		

Appendix 2: FSANZ response to issues raised in submissions to the October 2025 consultation paper

Note: Issues in column 1 of Tables 2 and 3 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: List of submitters to the consultation paper

Submitter	Abbreviation
Alcohol Beverages Australia	ABA
Australian Beverages Council	ABCL
Australian Food and Grocery Council	AFGC
Australian Retailers Association/National Retail Association	ARA/NRA
Complementary Medicines Australia	CMA
Confidential 1	
Confidential 2	
Department of Agriculture, Fisheries and Forestry	DAFF
Edith Cowan University	ECU
Individual submitter 1	IS1
Industry Submitter (name withheld)	IndS1
Lion	Lion
Mills Oakley	MO
Monde Nissin	MN
New South Wales Food Authority	NSWFA
New Zealand Beverage Council	NZBC
New Zealand Food and Grocery Council	NZFGC
New Zealand Food Safety	NZFS
Pernod Ricard New Zealand	PR
Public Health Association of Australia	PHAA
Queensland Health	QLDH
South Australia Health	SAH
Spirits and Cocktails Australia	SCA
Spirits New Zealand	SNZ
Suntory Oceania	SO

Table 2: Summary of issues concerning the draft variation proposed at the consultation paper

Issue raised	Submitter(s)	FSANZ response
Prohibition on caffeine as a food for retail sale, unless expressly permitted by the Code *At the consultation paper, the draft variation proposed a new prohibition - prescribed caffeine products.* *The draft variation would amend paragraph 1.1.1—10(5)(g) to;* *(a) remove the prohibition currently imposed by that paragraph;* *(b) replace that with a new prohibition on a food for retail sale being a prescribed caffeine product. A prescribed caffeine product will be defined in subsection 1.1.2—2(3) to mean any of the following: 1,3,7-trimethylxanthine (ie, caffeine); guarana extract.*		
Supports the new prohibition on the retail sale of guarana extract as a food. Requests a definition and extension of scope to all plant extracts high in caffeine. Recommends including *Ilex guayusa* leaf extract, Ilex paraguariensis (Yerba mate) extract and Green tea extracts (*Camellia sinensis*) in the definition of prescribed caffeine product, due to their high caffeine content. Submitter notes that given a different regulatory status between 'guarana extract' and other products made from guarana, clarity is required as to what 'guarana extract' is. Is guarana powder considered guarana extract? Is there a required method of extraction to be considered as guarana extract? Requests guarana extract is defined to separate guarana powder from guarana extract – so that it is clear what level of caffeine renders a substance a prescribed caffeine product.	NSWFA	FSANZ notes this support. FSANZ notes the Advisory Committee on Novel Foods view that green tea extract and yerba mate are novel foods (see ACNF Record of Views[20]) and no permission exists in the Code for addition of green tea extract as a novel food ingredient to food for sale. FSANZ has amended Standard 1.5.1 to make clear that a food for retail sale must not consist of, or have as an ingredient or component, caffeine from a novel food unless that novel food is listed in the Code as a permitted novel food, and any conditions of use prescribed by the Code for that novel food are complied with. After consideration of submissions, FSANZ decided to amend the draft variation to include a definition for guarana extract. The definition will in effect prescribe the sale of guarana extract by reference to its caffeine content. The definition also allows for any method of

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

Issue raised	Submitter(s)	FSANZ response
		extraction (including water and/or solvent extraction). Regarding distinguishing between a powder that is simply ground guarana seeds, versus a guarana powder that is produced using an extraction process, the definition sets a 5% cut off value for caffeine content. This will distinguish between the caffeine content (approximately 3% - 5% caffeine) in guarana seeds (or a powder prepared from grinding the seeds), compared with seeds that are subject to an extraction process (and sold in solid or semi-solid form including powder form). The definition's limits for caffeine align with the P1054 variation. Refer to section 2.3.1 in this report.
Recommends refining paragraph ((a) 1,3,7-trimethylxanthine) in the definition of prescribed caffeine content to clearly capture products that are pure or highly purified forms of caffeine. FSANZ could consider using the phrase 'has been concentrated, refined, or synthesised' as are used in the existing Code.	NSWFA	With respect to pure caffeine, FSANZ has amended the draft variation to clarify that the reference to 'caffeine' in the definition of prescribed caffeine product means 1,3,7-trimethylxanthine. Paragraph 1.1.1—10(6)(k) prohibits food for retail sale having as an ingredient or *a component*, caffeine from any source. For clarity, FSANZ has also amended the examples provided under paragraph 1.1.1—10(6)(k). The amendment clarifies that 'pure caffeine' is caffeine (1,3,7-trimethylxanthine) and that the addition of caffeine via plant extracts is not limited to guarana extract. See section 2.3.2 for more details.
Suggested an amended definition for 'prescribed caffeine product': **prescribed caffeine product** means any of the following: (a) 1,3,7-trimethylxanthine; (b) any botanical extract, concentrate, or derivative that: (i) contains caffeine; and (ii) is added to food primarily to increase caffeine content rather than for traditional	SAH	The definition of prescribed caffeine content is for the purposes of prohibiting the retail sale of caffeine and guarana extract. The suggested amendments relate to the addition of caffeine or foods containing caffeine, to other foods, and are therefore not

Issue raised	Submitter(s)	FSANZ response
culinary, flavouring, or nutritional purposes. **Note**: This includes but is not limited to extracts or concentrates of guarana, green tea, yerba mate, kola nut, and green coffee bean. It does not include cocoa, chocolate, coffee, or tea when used in traditional forms or concentrations."		appropriate. FSANZ has made several amendments to make clear that the prohibition on the sale of a food containing caffeine as an ingredient or component applies to plant extracts containing caffeine. See above response.
Noted inconsistencies when caffeine is referred to, e.g. the chemical name, 'pure caffeine', anhydrous caffeine. Drafting suggestion: 'product that is caffeine that has been concentrated, refined, or synthesised'.	NSWFA	FSANZ notes the submitter's comments and, for clarity, has made amendments to the draft variation to insert 1,3,7-trimethylxanthine after the word 'caffeine' in Items [2], [3] and [5] of the draft variation. Also refer to above response.
Supports amendments clarifying that guarana extract is a 'prescribed caffeine product' and is prohibited unless expressly permitted.	NZFS	FSANZ notes this support.
Supports prohibiting caffeine and guarana extract unless permitted, to prevent regulatory loopholes and address high-risk products.	PHAA	FSANZ notes this support.
Supports food for retail sale cannot be or contain a prescribed caffeine product (defined as caffeine and guarana extract).	DAFF	FSANZ notes this support.
Prohibition on a food for retail sale from containing caffeine as an ingredient in or component, unless expressly permitted by the Code *At the consultation paper, FSANZ proposed a clarification to the draft variation proposed at the 2nd CFS.* *The draft variation would amend subsection 1.1.1—10(6) to provide that, unless expressly permitted by the Code, a food for retail sale must not have caffeine **from any source** as an ingredient or a component.* *An example would be provided that reads:* *Food for retail sale that contains caffeine as an ingredient or component as a result of the addition of pure caffeine or of guarana extract.*		
Supports that guarana extract is not considered to contain caffeine naturally, that the prohibition applies to caffeine from all sources (pure caffeine or guarana extract).	DAFF	FSANZ notes this support.

Issue raised	Submitter(s)	FSANZ response
Suggests more consistent caffeine (including caffeine in total and caffeine from any source) terminology as does not have a clear distinction between caffeine as a product and as a substance present in food. For refined and pure and highly concentrated caffeine products the Code has terms. Submitter lists several areas of the Code with different references to caffeine that could be made consistent. Recommends reviewing and streamlining terminology throughout the Code, including std 2.6.4.	NSWFA	References in the draft variation were reviewed and updated to ensure consistency. See Items [2], [3] and [5] with the addition of (1,3,7-trimethylxanthine) after the word 'caffeine'. A broader review of terminology across the entire Code is out of scope of this proposal.
Preferred option is to create distinct, universally applicable terms throughout the Code: • "Total caffeine" = caffeine from all sources, measured analytically • "Added caffeine" or "prescribed caffeine" = caffeine from prescribed caffeine products (1,3,7-trimethylxanthine and guarana extract, plus other plant extracts containing caffeine)) • "Naturally occurring caffeine" = caffeine inherent in cocoa, chocolate, coffee, and tea in their traditional forms.	SAH	Refer to above response.
P1056 intent is to address risks associated with caffeine particularly among sensitive sub-populations (children, adolescents, and pregnant or lactating women). Alcohol products should not be consumed by these sub-populations in any circumstances, and alcohol products display warning labels to this effect. Recommends exempting alcohol from the proposed prohibition on guarana extract. Alcoholic beverages should be treated consistently with FCBs and FSSF. Provides the following reasons: • P1056 does not present evidence of harm from guarana in alcohol and is a disproportionate regulatory response to the identified risk and inconsistent with FSANZ's risk assessment where caffeine exposure not the plant source is the relevant risk factor.	Lion	The prohibition on the addition of caffeine to all foods (which included alcoholic beverages) (except where explicitly permitted) was proposed at the 1st CFS and extensively consulted on (see section 2.1 of this report). The prohibition was based on a safety assessment that identified several risks to the general population (see section 2.2 of this report) as well as to identified sensitive sub-populations. The prohibition was broadly supported by submitters at both the 1st and 2nd CFS (section 2.3.2 of this report). ' FSANZ's intent at the 2nd CFS and the consultation paper was that all forms of highly concentrated

Issue raised	Submitter(s)	FSANZ response
• FSANZ may not be fully aware of the breadth of products that rely on guarana extract as a source of caffeine at very low levels or as a flavouring. • Encourage minimum effective regulation that balances the need to ensure products are safe while minimising cost and regulatory burden. • Alcoholic drinks are highly regulated that includes age restrictions and many layers of consumer protection. Suggests possible unintended consequences of P1056 including the risk that guarana containing beverages being reformulated to contain more caffeine (i.e. regulate under the FCB or FSSF standard).		caffeine would be captured under the prohibition, regardless of the source (sections 2.2.1.2, 2nd CFS and 2.2.1 of the consultation paper). Submissions identified that guarana extract can be a source of highly concentrated caffeine and, as such, is one of the products identified by both the P1054 and P1056 risk assessment as posing a risk to public health. To clarify which products using guarana will be impacted, FSANZ has amended the draft variation to make clear when guarana extract is prohibited as an ingredient in a food for retail sale (see section 2.3.2.3 of this report). The definition allows for the use of guarana seeds or powder, and guarana extracts provided the caffeine content complies with the 1% and 5% limits set out in the draft variation. FSANZ considers this to be a risk proportionate measure which will allow for the use of guarana extract (containing similar levels to those occurring naturally or in coffee products) consistent with the limits established under P1054. In reaching this conclusion, FSANZ has had regard to: • well established concerns drinking alcohol that is mixed with caffeine could lead to more drinking, injury, and risks to health Effects of Mixing Alcohol and Caffeine | Alcohol Use | CDC • evidence that caffeine when consumed at safe levels is unlikely to mask the subjective perception of alcohol intoxication which could lead to increased risk-taking behaviour when alcohol is consumed at moderate levels Scientific Opinion on the safety of caffeine. • industry statements (here and in submissions below) that guarana is being used as an ingredient at very low levels • based on product scans and considering the proposed new definition, it is anticipated that the

Issue raised	Submitter(s)	FSANZ response
		regulatory impact will be minimal and will assist with enforceability and reduce the regulatory burden for industry. FSANZ maintains that for other caffeine containing plant extracts, the use of these extracts will be subject to the prohibition and those that are novel foods for the purpose of the Code would require pre-market assessment. Should manufacturers wish to use caffeine (from any source) in alcoholic beverages at levels consistent with FCBs or FSSFs, an application would need to be made to FSANZ. Such an application would likely require a broader policy consideration of the consumption of caffeine in alcohol by Australian and New Zealand governments. Early engagement with government would be necessary.
Recommend FSANZ: 1. Exempt alcohol beverages from the proposed prohibition – Alcohol beverages should be treated consistently with FCBs and FSSFs. 2. Refine the definition of permitted caffeine sources - ensure flavouring ingredients containing incidental caffeine are not captured and avoid unnecessary restriction on innovation. 3. Apply an evidence-based and proportionate approach - focus on sources of demonstrated risk. Extensive research should precede any bans. Consistency with s18 of the FSANZ Act. ***Concerns with proposed guarana ban*** The proposal to limit or ban the use of guarana is not based on evidence and has not undergone usual FSANZ consultation. There was no direct engagement with the alcohol sector. Appears FSANZ may not be fully aware of the breadth of products that rely on guarana extract as a source of caffeine at very low levels.	SNZ	See above response regarding: • Treating alcohol beverages consistently with FCBs/FSSF • Previous consultations/engagement with the public on the prohibition on the addition of caffeine to all food (except where explicitly permitted). As stated in sections 2.2.1.2 of the 2nd CFS, 2.2.1 of the consultation paper and 2.3.2 of this report, FSANZ maintains that the intent of the prohibition was to prohibit the addition all forms of highly concentrated caffeine to food. • Demonstrated risk of the addition of caffeine to food to both the general population and sub populations FSANZ does not agree that there is no risk from products that contain highly concentrated caffeine ingredients. • Revisions FSANZ has made to the draft variation to provide definition of guarana

Issue raised	Submitter(s)	FSANZ response
Believes the proposed ban on caffeine from guarana and other plant extracts will have unintended consequences for alcohol beverages not anticipated by FSANZ and were not mentioned in the earlier consultations. No credible evidence produced that would show that spirit-based products containing caffeine or guarana are causing risk to the target subgroups - children, adolescents, and pregnant or lactating women. These groups should not be consuming alcohol and FSANZ will be well aware of the broad and deep array of regulations, laws and industry management practices that restrict, educate and promote zero consumption to these groups. If alcohol use by these groups exists it indicates a broader issue. Levels of guarana used in RTDs, for example, are lower than the levels used in many FSSFs and FCBs, which will continue to be permitted. Alcohol products are only sold within a heavily regulated environment that includes strict age restrictions and many layers of consumer protections. The proposal represents regulatory overreach and would impose unfair and inconsistent burdens on the sector. Principle from FSANZ 2019 report that only those products posing a demonstrated public health and safety concern are captured, and that the approach does not result in unintended consequences for other foods, appears overlooked. ***FSANZ Act objectives in relation to proposal to prohibit guarana in alcohol beverages (some covered above):*** - Protection of public health and safety – no public health gain, risk management measures already in place, when weighed against caffeine consumption from tea, coffee, FCBs and FSSFs – the proposed prohibition will make an infinitesimally small and therefore meaningless reduction in population level caffeine exposure - Provision of adequate information relating to food to enable consumers to make informed choices – present labelling requirements adequate - Need for standards to be based on risk analysis using the best		extract, which will provide clarity on when guarana extract will be captured by the prohibition. Based on product scans, it is anticipated the regulatory impact will be minimal. Flavourings are regulated as food additives, and the permission for a food additive (flavouring) to contain caffeine is limited to use in cola beverages. Coffee flavourings (regulated as food additives) are not permitted to contain caffeine. Coffee flavours do not necessarily contain caffeine. This proposal does not impact on the current ability under the Code to mix compliant foods together. See section 4 of this report for how FSANZ has met its objectives under the FSANZ Act, and section 3.5.3 of the 1st CFS (FSANZ 2022) for an outline of how FSANZ has had regard to any written policy guidelines. There are three relevant to this proposal. See Appendix A of the P1054 Final consideration report, section 1.4.4 of the 2nd CFS and section 1.4.5 of this report for alignment with international jurisdictions. FSANZ submitted WTO notifications for both the 2nd CFS and the consultation paper. One submission was received, unrelated to trade impacts (see Table 3, Appendix 3 of this report). The merging of risk management and risk assessment teams has strengthened FSANZ's capability to undertake risk analysis consistent with Codex.

Issue raised	Submitter(s)	FSANZ response
available scientific evidence – believe risk analysis as per Codex guidelines is difficult to achieve at FSANZ since merger of risk management and risk assessment teams. FSANZ should reflect on how it best achieves consistent approaches to both functions given the revised structure. - Promotion of consistency between domestic and international food standards – note absence of Codex standard for caffeine is instructive. FSANZ has not identified any other countries/regulators expressly prohibiting guarana in alcohol beverages. The proposed prohibition does not promote consistency but will achieve the opposite. - Desirability of an efficient and internationally competitive food industry - the proposed prohibition is arguably WTO SPS non-compliant due to the lack of any appreciable gain in public health, trade barrier. Trading partners would be required to reformulate products or avoid exporting them to Australia and New Zealand. Impacts on exporters not considered in cost benefit analysis. The cost benefit analysis mentions the branded food database without describing the completeness or limitations of that source of information, question the statement that only five affected products were identified. - Written policy guidelines – none particularly relevant.		
Guarana extract is used in several alcoholic beverages in New Zealand. Product names provided. Submitter questions whether the proposed prohibitions will apply to all alcoholic beverages containing any amount of caffeine, regardless of the existing requirement to state 'contain caffeine', their restricted sale to people over the age of 18 years and the mandatory pregnancy warning label?	NZFGC	See above response.
Submitter's product portfolio includes products that contain coffee extract and cola. P1056 has consequences for the alcohol beverage industry that do not appear to have been considered and engaged with. Seeking an exemption for alcohol beverages from the proposed amendments for P1056 as there is no additional	PR	Proposal P1056 does not impact the current Code provisions regarding the mixing of a cola beverage with other foods. See above response to Lion and SNZ regarding the risk to the general population (not just sub-

Issue raised	Submitter(s)	FSANZ response
protection provided by the provisions as children, pregnant and lactating women should not be drinking alcohol.		populations) from caffeine in foods.
No evidence cited showing how the ban on guarana extract (in alcohol) would improve public health and safety. The sensitive groups identified are already prohibited from purchasing alcoholic beverages or advised against consuming them. The quantities of guarana used in spirits-based beverages are typically lower than can be found in sports drinks and FCBs which would not be addressed by P1056. The Code already requires mandatory 'contains caffeine' advisory labelling on beverages containing guarana. This existing requirement enables caffeine-sensitive consumers or those seeking to limit caffeine intake can make informed choices.	SCA	See above response to Lion and SNZ regarding risks to the population from caffeine in food and the draft variation amendments on guarana extract.
In its 2019 report, FSANZ stated it is important that only those products posing a demonstrated public health and safety concern are captured and that the approach does not result in unintended consequences for other foods. Guarana extract is present in a large number of beverages, often at very low levels meaning a ban on its use would have a significant impact on the industry.	SCA	See above response to Lion add SNZ regarding risks to the population from caffeine in food and the draft variation amendments on guarana extract.
P1056 does not identify other regulatory schemes prohibiting guarana in alcoholic beverages. Submitter considers Australia and New Zealand are taking an outlier position out of step with global standards and would impose a damaging and unnecessary trade barrier. Recommend exempting alcoholic beverages from the proposed prohibition and treat them consistently with other beverages products.	SCA	See above response to SNZ regarding consideration of other international jurisdictions.
Agree consumer safety is important and that regulatory measures enable industry innovation. This can be achieved without introducing exhaustive lists or creating unnecessary barriers to the use of caffeine sources that are not novel and are not explicitly listed in the Code. Such restrictions could limit product development and consumer choice without delivering additional safety benefits.	SO	See above response to Lion and SNZ regarding risks to the population from caffeine in food, submitter support for the prohibition and the draft variation amendments on guarana extract. FSANZ notes that should food businesses wish to add caffeine to foods where there is no specific permission, or to amend existing permissions, an

Issue raised	Submitter(s)	FSANZ response
		application to amend the Code could be made to FSANZ.
The ban on caffeine from guarana and other plant extracts could unintentionally affect alcohol beverages and there was no direct engagement with the alcohol sector regarding the guarana prohibition. FSANZ may not be fully aware of the breadth of products relying on guarana extract as a source of caffeine at very low levels. FSANZ's original principle was to only regulate products posing a demonstrated public health risk and avoid unintended consequences. The current proposal appears to overlook this, capturing products with incidental caffeine and no identified health risk. When considered in the context of section 18 of the FSANZ Act, concerns are raised about how it aligns with the objectives of the Authority. There is no evidence that prohibiting guarana in alcohol would improve public health and safety. Queries whether the proposal meets Codex risk analysis principles. FSANZ has not identified any international regulators that prohibit guarana in alcohol, so the proposal would reduce consistency with global standards and could create trade barriers. The proposal targets risks for sensitive groups, but these groups should not be consuming alcohol anyway and industry makes efforts to prevent them doing so. If there is evidence of alcohol use by these groups, it indicates an issue beyond concerns about caffeine intake and warrants targeted support. Guarana levels in ready-to-drink alcohol products are lower than in many sports drinks and formulated caffeinated beverages, which will still be allowed. Alcohol products are sold in a highly regulated environment with strict age restrictions and consumer protection and no evidence is presented that alcohol products with guarana have caused harm. Recommends:	ABA	See above response to Lion and SNZ regarding: • Previous consultations/engagement with the public on the prohibition on the addition of caffeine to all food (except where explicitly permitted). As stated in sections 2.2.1.2 of the 2nd CFS, 2.2.1 of the consultation paper and 2.3.1 of this report, FSANZ maintains that the intent of the prohibition was to prohibit the addition all forms of highly concentrated caffeine to food. • Demonstrated risk of the addition of caffeine to food to both the general population and sub populations FSANZ does not agree that there is no risk from products that contain highly concentrated caffeine ingredients. • Revisions FSANZ has made to the draft variation to provide definition of guarana extract, which will provide clarity on when guarana extract will be captured by the prohibition. Based on product scans, it is anticipated the regulatory impact will be minimal. • Alignment with FSANZ's objectives under the FSANZ Act, international regulators and Codex risk analysis principles. • Based on the above, FSANZ does not consider it necessary to provide an exemption for alcoholic beverages. FSANZ maintains a 2 year transition period is appropriate (see section 5 of the Approval Report) and FSANZ has made drafting amendments to the definition of guarana extract in response to stakeholder feedback to clarify the intent of the proposed changes and to demonstrate that the

Issue raised	Submitter(s)	FSANZ response
• **Exempt alcohol beverages from the proposed prohibition**—treat them consistently with FCBs and FSSF. • **Refine the definition of permitted caffeine sources**—ensure incidental caffeine in flavourings is not unnecessarily restricted. • **Apply an evidence-based, proportionate approach**—focus on sources of demonstrated risk and conduct thorough research before bans. • **In addition to exemption of alcohol, allow a four-year transition period**— amendments likely to impact products in market, to accommodate reformulation which is complex and takes longer than labelling changes. • **Require a thorough Regulatory Impact Statement (RIS)** - due to shortcomings in the current cost-benefit analysis, a full RIS should be developed and consulted on which details the impact for all products in the market.		regulatory burden is significantly lower than some submitters anticipated.
The term 'extract' is considered too vague to reliably indicate caffeine content from botanical sources. Applies to guarana extract. Not all extracts (including guarana, green tea, and coffee extracts) contain concentrated caffeine, and the term alone is insufficient for regulatory purposes. Reliance on 'extract' without specifying expected naturally occurring caffeine levels may not safeguard consumers effectively.	NZBC	See response above regarding the definition of guarana extract.
Cautions against focusing regulatory changes solely on 'guarana extract' as this creates uncertainty about the treatment of other ingredients like green tea and coffee extracts. These other extracts often do not contain concentrated caffeine and have a long history of safe use as food ingredients.	NZBC	See section 2.3.1 and 2.3.2 of this report and the definition of guarana extract.
Support revisions so that the prohibition applies to caffeine regardless of origin as consumers do not distinguish between caffeine sources when assessing risk. This will simplify compliance and reduce ambiguity for manufacturers and retailers and provide clearer guardrails for innovation.	ARA/NRA	FSANZ notes this support.

Issue raised	Submitter(s)	FSANZ response
The Code must explicitly state caffeine must not be added to food (or sold as a food) unless specifically permitted by the Code including natural caffeine sources in addition to guarana.	ECU	FSANZ notes this comment – this is the intention of the proposed draft variation.
Caffeine from natural sources (as a concentrated extract, including proprietary blends) should be designated as high-risk foods and automatically classified as novel foods. Market reports show growth in 'clean label' plant based energy drinks and other beverages including natural sources of caffeine. Submitter seeks clarity on whether there is any restriction on these natural source caffeine extracts/concentrations/proprietary blends being added as ingredients or as flavouring to any or all general foods, including formulated beverages, milk or milk alternative beverages, breakfast drinks. Submitter concerned that high caffeine beverages containing 'novel' natural source caffeine are already on the market, and it would be up to jurisdictions to remove products from the market.	ECU	FSANZ notes this comment, see sections 2.3.1 and 2.3.2 of this report, and the revised drafting (Attachment A). Standard 2.6.4 already requires caffeine from all sources to be counted/included. Therefore, a FCB can contain singularly or in combination, caffeine or a plant extract that is a source of caffeine. The FCB standard sets compositional limits for caffeine, regardless of source. Under the approved draft variation, caffeine (regardless of source) can only be added to food where permitted. This clarity means jurisdictions can take enforcement action against non-compliant products that are not a FCB or FSSF, that contain caffeine, either added as directly as caffeine, or via a plant extract or concentrated source from a plant.
Item [2] recommends replacing the term 'pure caffeine' in the proposed Example with 'product that is caffeine that has been concentrated, refined, or synthesised' for consistency in terminology. Submitter supports the proposed draft variation's use of the same term ('caffeine from any source') in the general prohibition as proposed in paragraph 1.1.1—10(6)(k) and the explicit permission for FSSF (as proposed in subparagraph 2.9.4—3(1)(c)(ii)). This structure is important to remove doubt that 'caffeine from any source' is prohibited in all foods unless explicitly permitted. The consistent term should be used in relation to permission in other foods as well (e.g. FCB).	NSWFA	See section 2.3.2 of this report.
Recommends clarifying that *Ilex guayusa* leaf extract, *Ilex paraguariensis* (Yerba mate) extract and Green tea extracts	NSWFA	FSANZ notes the ACNF view that green tea extract and yerba mate are novel foods (see ACNF Record

Issue raised	Submitter(s)	FSANZ response
(*Camellia sinensis*) are prohibited sources of caffeine in FSSF (subparagraph 2.9.4 — 3(1)(c)(ii) (Item [11]) and/or Paragraph 2.9.4 — 3(2)(c)).		of Views[21]) and no permission exists in the Code for addition of green tea extract as a novel food ingredient to food for sale. FSANZ has amended Standard 1.5.1 to make clear that a food for retail sale must not consist of, or have as an ingredient or component, caffeine from a novel food unless that novel food is listed in the Code as a permitted novel food, and any conditions of use prescribed by the Code for that novel food are complied with.
Supports prohibition of guarana extract as an ingredient, unless expressly permitted. Requests a definition. Given a different regulatory status between 'guarana extract' and other products made from guarana, clarity is required as to what 'guarana extract' is. Is guarana powder considered guarana extract? Is there a required method of extraction to be considered as guarana extract?	NZFS	See section 2.3.2 of this report, and the definition of guarana extract.
Strongly supports clarifying that prohibitions apply to caffeine from all sources, including undiscovered plant extracts which may not be classed as novel foods. Calls for premarket assessment of new caffeine sources. This prevents industry circumvention of regulations, ensures equal regulatory treatment of pure caffeine and plant-derived caffeine and is consistent with WTO "treat like risk alike" expectation. Implement consistent definitions for 'natural occurrence' and 'added caffeine'.	PHAA	FSANZ notes this support. FSANZ maintains that for other caffeine containing plant extracts, the use of these extracts will be subject to the prohibition and those that are novel foods for the purpose of the Code would require pre-market assessment. FSANZ did not consider definitions for the terms 'added caffeine' and 'natural occurrence' in the Code necessary as 'added caffeine' only occurs once in the Code relating clearly to cola beverages. Natural occurrence occurs once in subsection 1.1.1—10(7) and an example has been provided in the draft variation to make clear when a substance is considered 'by natural occurrence'.

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

Issue raised	Submitter(s)	FSANZ response
Notes that the prohibition relates to 'caffeine from any sources', but notes there is inconsistent application of the phrase 'from any source'. Examples provided.	SAH	See above response.
Considers that the status of 'extracts' from natural sources following the example to 1.1.1—10(7) is not clear and risks potential restrictive and inconsistent interpretation. The use of the term 'only' in reference to cocoa, chocolate, coffee, or tea is further complicated by the proposed subclause 1.1.1—10(7A) specifying that guarana extract is not 'caffeine from a natural source'. Complexity of extracts is illustrated by ACNF records which show different views based on technical factors like selective enrichment or altered composition. Recommends retaining the existing caffeine limits (1% for liquids, 5% for solids/semi-solids) for all foods, regardless of source. This avoids unnecessary complexity of having to differentiate sources of caffeine and the need for examples and subclause 1.1.1—10(7A), simplifies compliance, and prevents restrictive interpretations.	AFGC	See section 2.3.3 of this report and the revision to the example under subsection 1.1.1—10(7) – explaining that cocoa is an example of a food containing caffeine by natural occurrence. See also the revisions to subsection 1.1.1—10(7A) to address submitter concerns.
Considers full prohibition on guarana extract is overly restrictive; suggests risk-management measures (e.g., caffeine limits, ingredient specs, mandatory warnings) instead as singling out guarana extract may create ambiguity for other caffeine-containing plant extracts (e.g., green coffee bean). Pre-market approval for all new caffeine-containing plants could hinder innovation; recommends clearer terminology like 'caffeine isolate from a plant source' rather than singling out guarana extract. Requests the rationale for the prohibition to be clearly articulated and supported by risk assessment evidence if going ahead.	CMA	Guarana extract was the primary extract identified by FSANZ that could be a highly concentrated source of caffeine and thus required a regulatory risk management approach. FSANZ maintains that for other caffeine containing plant extracts, the use of these extracts will be subject to the prohibition and those that are novel foods for the purpose of the Code would require pre-market assessment. See sections 2.3.1 and 2.3.2 on FSANZ's discussion on guarana extract. Pre-market approval by FSANZ that includes a risk-based public health and safety assessment for novel foods ensures the safety of novel foods before they can be a food for retail sale or an ingredient in a food for retail sale in Australia and New Zealand. The purpose of this assessment is to evaluate the

Issue raised	Submitter(s)	FSANZ response
		potential impact of permitting the novel food on public health and safety, a requirement under the FSANZ Act.
Mandatory pre-market assessment for all new caffeine-containing plants could inhibit innovation and significantly extend time to market for emerging food products. Suggests risks for compositional limits and advisory statements instead could manage the risk of caffeine-containing plant extracts.	CMA	FSANZ notes this comment. See above response regarding pre-market assessment for novel foods.
FSANZ should ensure flavouring ingredients containing incidental caffeine are not captured to ensure no unnecessary restriction on innovation	Lion	This proposal does not impact on the current ability under the Code to mix compliant foods together e.g. adding coffee to a cake or beverage. Further, the prohibitions imposed by the draft variation in subsection 1.1.1—10(6) apply subject to the exemption provided by subsection 1.1.1—10(7). That subsection provides that subsection 1.1.1—10(6) does not apply to a substance that is in a food for sale, or in an ingredient of a food for sale, by natural occurrence. The above would mean the proposed prohibition of a food for retail sale containing, as an ingredient or component, caffeine from any source would not apply to caffeine in a food for retail sale, or in an ingredient of a food for retail sale, by natural occurrence. Given the above, FSANZ considers that the draft variation sufficiently allows for innovation in food products. FZANZ also notes there is only one food additive (flavouring) permission in the Code for caffeine (kola beverages).
Raised issue of prescriptive nature of blanket prohibition on caffeine from any source with limited exceptions for ‘natural occurrence’. Consider it:	MN	FSANZ has clarified further what natural occurrence means by way of an example in following subsection 1.1.1—10(7).

Issue raised	Submitter(s)	FSANZ response
• Creates ambiguity around what constitutes “natural occurrence,” especially for plant extracts (guarana would be prohibited despite being a traditional, naturally derived ingredient). • Risks stifling innovation in functional beverages and juice-based products • Doesn’t address primary sources of caffeine intake (coffee, tea, soft drinks) (90% of consumption). Lack of clear thresholds for guarana, concentrated coffee and tea creates regulatory uncertainty, complicates ROI calculations and product development timelines. Creates confusion and inconsistency in functional beverages including juice or tea-based products. Consider the previous outcomes-based approach (P1054) offered clear, enforceable thresholds (e.g., 1% in liquids, 5% in solids) without unnecessary complexity. Recommend FSANZ: • Retain outcomes-based approach with clear caffeine limits (1 and 5% limits). • Provides enforceable, science-based thresholds instead of subjective interpretations of “natural occurrence.” • Focus on actual risk drivers (e.g., pure caffeine powders) rather than plant-based ingredients. • Ensure regulatory clarity and consistency to reduce industry burden.		Whilst guarana contains naturally occurring caffeine, it can also, when extracted, be a highly concentrated source of caffeine. In line with submitter responses to the 1st and 2nd CFS and the intent of both P1054 and P1056, a prohibition on sources of highly concentrated forms of caffeine is warranted. Caffeine content in guarana can be higher than that in coffee and thus warrants a different regulatory response. FSANZ considers the FCB and FSSF standards allow for innovation in caffeinated beverages. In response to submissions to the consultation paper and FSANZ has included a definition for guarana extract which retains the 1 and 5% limits. This will assist with enforceability and reduce the regulatory burden for industry.
High caffeine coffee beverages can contain caffeine from high caffeine extracts from natural sources, such as guarana.	ECU	FSANZ notes that in accordance with the approved draft variation, caffeine cannot be added to any beverages (unless permitted elsewhere in the Code) under paragraph 1.1.1—10(6)(k). These beverages would comprise coffee (as the caffeine in coffee is naturally occurring) as the primary caffeine source, but may be mixed with water, milk, sugar, etc. Other

Issue raised	Submitter(s)	FSANZ response
		sources of caffeine may also be present, such as from cocoa, or guarana (guarana extract over the 1 and 5% concentration limits would not be permitted). Any beverage that meets the criteria set out in the new subsection 1.1.2—3(2) (see Item [7], Attachment A to this report) would be required to be labelled in accordance with the approved draft variation.
P1056 does not adequately protect children under 18. Current market trends indicate rapid growth of 'clean label' energy drinks and natural caffeine sources (e.g., guayusa, yerba mate). • Novel caffeine sources entering market without proper regulation. • Enforcement challenges for novel foods and emerging sources in the US e.g., guayusa extract. FSANZ should: • Mitigate risk from other new caffeine rich extracts ingredients (i.e. caffeine from natural sources including green coffee bean, Yerba mate, Guayusa tea extract). Seeks clarification on whether there is any restriction on these natural sources of caffeine. Notes difficulty with enforcing novel foods that are already on the market as it is up to jurisdictions to actively demonstrate that a product is unsafe. • Automatically designate ingredients such as green coffee bean extract, green tea extract, Yerba mate as novel foods as they contain other components that haven't been assessed as safe (provided product examples containing caffeine from natural plant sources).	ECU	The Code does not permit a novel food for retail sale or addition to food for retail sale unless it is listed in section S25—2. Premarket assessment is required for any novel food that does not meet those requirements. Whether or not a caffeine containing plant meets the definition of a novel food is out of scope for this proposal.
Caffeine from novel food prohibited unless novel food permitted. *At the consultation paper, the draft variation proposed to amend section 1.5.1—3 by adding subsection 1.5.1—3(3).* *The new subsection would provide that, despite any other provision of the Code, a food for retail sale must not consist of, or have as an ingredient*		

Issue raised	Submitter(s)	FSANZ response
or component, caffeine from a novel food unless that novel food has been listed in section S25—2 as a permitted novel food and any conditions of use specified in that section for that food are complied with.		
Does not support proposed revisions on the basis that it may cause unnecessary confusion and the novel food provisions are sufficient.	ABCL	FSANZ notes this comment, however FSANZ is maintaining its approach (with an amendment as per response below). The new subsection provides greater clarity regarding novel foods that are sources of caffeine.
Recommends clarifying that the prohibition is not about adding pure and highly concentrated caffeine products manufactured from novel food, but about the presence of caffeine as a component of novel food that is used as an ingredient. Queries why the drafting contains the phrase 'consist of'. Taken together, the drafting 'a food for retail sale must not consist of, or have as an ingredient or component, caffeine from a novel food' in subsection 1.5.1 —3(3) can be amended to 'food for retail sale must not have as an ingredient or a component, caffeine as a result of the addition of novel food'.	NSWFA	FSANZ agrees. See section 2.3.2 of this report and the amendment to subsection 1.5.1—3(3) to remove the words 'consist of'.
Caffeine in a food by natural occurrence *At the consultation paper, the draft variation proposed to provide clarification in Standard 1.1.1 by inserting the following words and example in the Code after subsection 1.1.1—10(7):* *Caffeine present in a food for sale, or in an ingredient of a food for sale, only as a result of the addition of cocoa, chocolate, coffee or tea; is caffeine that is in the food for sale or the ingredient by natural occurrence. The caffeine occurs naturally in the cocoa, chocolate, coffee or tea. Caffeine in a food for sale, or in an ingredient of a food for sale, as a result of the addition of pure caffeine; is not in the food for sale or the ingredient by natural occurrence.* *The draft variation would also include new subsection (7A) in section 1.1.1—10. The new subsection will state that subsection 1.1.1—10(7) does not apply to guarana extract.*		
Listing only cocoa, chocolate, coffee and tea as examples of ingredients containing caffeine 'by natural occurrence' is too narrow and could be misinterpreted as an exhaustive list. Recommends removing or amending the example to avoid excluding other caffeine-containing plants. If retained, consider removing the word	ABCL	FSANZ notes this comment. FSANZ has amended the drafting to address the submitters comment.

Issue raised	Submitter(s)	FSANZ response
'only' in the example in the draft variation.		
Consider excluding guarana extract from being considered 'naturally occurring' caffeine is not justified given other plant extracts contain caffeine and creates confusion. Distinguishing sources of caffeine based on plant species/extraction method is not risk proportionate. Caffeine risk depends on the amount of caffeine consumed, not the source and the term 'extract' does not reliably indicate caffeine concentration. For the regulation of extracts, suggests a principle-based approach to the regulation of extracts. Instead of ingredient specific exclusions, propose if an extract's composition is no longer representative of the original plant, it should be considered 'added caffeine'. Suggests also retaining the 1 and 5% (P1054) provisions in the Code in 1.1.1—10(5)(g).	ABCL	See sections 2.3.1 and 2.3.2 of this report for FSANZ's decision on a definition of guarana extract. FSANZ agrees that caffeine risk depends on the amount of caffeine consumed. The definition provides clear concentration limits for when guarana extract is captured by the prohibition. With the exception of guarana, FSANZ considers many other caffeine containing plant extracts may be novel foods. The determination of whether an extract is a novel food or not is out of scope for P1056. FSANZ is maintaining the approach at the 2nd CFS with respect to the P1054 variation (see section 2.3.4 of this report).
Support restricting retail sale of guarana extract where it is intended to prevent the addition of concentrated caffeine for stimulant purposes. However, applying a blanket prohibition without appropriate exemptions for when guarana is naturally occurring and has a legitimate commercial use and when it meets established safety thresholds would risk unnecessary reformulation, relabelling and stock management.	ARA-NRA	See section 2.3.1 of the Approval Report, and the new definition of guarana extract. The exemption in 1.1.1—10(7) will allow for the use of guarana seeds or powder (i.e. when the caffeine in the guarana is naturally occurring), provided the caffeine content complies with the draft variation.
Supports clarifying 'naturally occurring' caffeine but finds current explanation unclear. • Lack of clarity on non-extracted guarana, yerba mate, and other botanicals. • Green tea extract with added caffeine • Ambiguity in defining "highly concentrated caffeine source." Requests: • Clear definitions for "naturally occurring" caffeine. • Definition for 'highly concentrated caffeine source' – such as 'caffeine isolate from a plant source' or similar	CMA	See sections 2.3.2 and 2.3.3 of this report for FSANZ's discussion on novel foods and the definition of guarana extract and final decision on this issue. FSANZ considers the amendments allow for clear interpretation of non-extracted guarana and other caffeine containing plant extracts. Refer also to the ACNF view that green tea extract is a novel food (see ACNF Record of Views) 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 of the 2nd CFS for further

Issue raised	Submitter(s)	FSANZ response
• Examples of plant extracts with elevated caffeine levels.		discussion on extracts and novel foods).
Requests inclusion of an additional example in 1.1.1—10(7) or 1.1.1—10(7A) to illustrate other plant extracts with elevated or standardised caffeine levels to better reflect the policy intent in the consultation paper. This would clarify what constitutes 'unnaturally' elevated caffeine levels and assist with consistent application of the regulation and reduce ambiguity for industry.	Industry Submitter (name withheld)	See section 2.3.2 and 2.3.3 of this report for FSANZ's discussion on novel foods and the definition of guarana extract and final decision on this issue.
• Recommends adding more guidance as to what is considered as the presence 'by natural occurrence' in the Code and/or Explanatory Statement, in line with FSANZ's statement in the consultation paper page 19 : FSANZ's position was and is subsection 1.1.1—10(7) does not apply to or permit plant extracts with 'unnaturally' elevated levels of caffeine levels (such as guarana extract) as the latter is not naturally occurring caffeine'. The clarification that 'unnaturally' elevated levels of caffeine is not naturally occurring caffeine will assist with interpretation of subsection 1.1.1—10(7). • Recommends adding a Note to refer to the proposed subsection 1.5.1 — 3(3), to inform readers that the presence of caffeine by natural occurrence in food for retail sale may be prohibited by subsection 1.5.1 — 3(3). • Recommends replacing the term 'pure caffeine' in the proposed Example with 'product that is caffeine that has been concentrated, refined, or synthesised' for consistency in terminology	NSWFA	See sections 2.3.2 and 2.3.3 of this report for FSANZ's amendments regarding natural occurrence. FSANZ considers the amendments allow for clear interpretation of subsection 1.1.1—10(7).
Recommends retaining the caffeine concentration limits currently in 1.1.1—10(5)(g) of the Code. Does not support proposed changes to 1.1.1—10(7) and the addition of 1.1.1—10(7A), arguing these would make regulations more prescriptive and confusing, potentially inhibiting innovation.	NZBC	See section 2.3.4 of this report, and the rationale for removing the P1054 variation.
Questions how other caffeine-containing plant extracts (like coffee extracts or green coffee bean extracts) will be regulated, as only guarana has been singled out. Prohibiting their use on the basis of	NZFGC	See section 2.3.2 of this report, and the definition of guarana extract. This clarifies that the example is

Issue raised	Submitter(s)	FSANZ response
their assumed increased caffeine content may have unintended consequences such as stifle innovation and make some low-caffeine products non-compliant. Argues that the term 'extract' is not specific enough to determine concentrated sources of caffeine, as not all extracts concentrate caffeine, and some guarana extracts provide only a small amount of caffeine, significantly less caffeine than permitted in cola beverages. Recommends, because of ambiguity introduced by using the term extracts and singling out guarana as a source when there are over sixty plants that contain naturally occurring caffeine, retaining the 1% and 5% caffeine limits for all retail foods, regardless of caffeine source, to provide clarity and future-proofing.		not limited to guarana extract.
Agrees the exception for caffeine 'by natural occurrence' should not apply to guarana extract, providing regulatory clarity.	NZFS	FSANZ notes this support.
Supports adding examples in the Code to clarify when caffeine is considered naturally occurring. Recommends more specific examples, especially regarding traditional processing methods for coffee and tea, to reduce ambiguity. Suggests removing the word 'only' from the example to avoid misreading provision as limiting naturally occurring caffeine to just four foods. The proposed drafting introduces new instances of the word 'coffee'. These are intended to encompass coffee that has undergone processing (such as extraction or extraction and concentration) before being consumed, reconstituted, or added to food. However, the Code's definition for coffee describes roasted or unroasted coffee beans or ground coffee (Standard 1.1.2—3). We suggest considering whether these differences in processing may affect the interpretation of 'coffee' in the drafting. Submitter noted previous discussion in the submission how this could be clarified for the proposed example inserted after 1.1.1—10(7).	NZFS	See section 2.3.3 of this report regarding the revisions to the draft variation to address submitter comments.
Supports the amendment for natural occurrence. Recommends stronger guidance for naturally occurring caffeine in	PHAA	See section 2.3.3 of this report regarding the revisions to the draft variation to address submitter

Issue raised	Submitter(s)	FSANZ response
foods versus caffeine-rich extracts, e.g. clearly define naturally caffeinated foods and foods where natural extracts are added, ensure no caffeine-rich extracts are treated as being of natural occurrence.		comments.
Supports the exemption for naturally occurring caffeine in food, with examples provided.	DAFF	FSANZ notes this support.
Supports clarity provided by this revision for guarana extract but ambiguity remains for all other plant extracts high in caffeine, queries the rationale for solely relying on the novel food provisions. Noting P1024 is on hold, and that it has been previously published by FSANZ that the novel food definitions include ambiguous terms that create uncertainty in the marketplace unless supported by additional drafting. Submitter suggests: The inclusion of non-traditional plant sources into 1.1.1—10(7A) so that use in general foods would require permission. Three examples from the ACNF could be added: • Ilex guayusa leaf (~20% caffeine) • Ilex paraguariensis (yerba mate) extract standardised to contain 2% caffeine • Green tea extract (camellia sinensis) Specific drafting in relevant standards (i.e. FCBs, FSSF) that provides explicit permission for only defined permitted caffeine sources would be required to ensure the suggested revisions to 1.1.1—10(7A) are not mis-interpreted as a permission.	NSWFA	See section 2.3.2 of this report, and the definition of guarana extract. An application can be made to FSANZ if a manufacturer wishes to permit a new caffeine containing plant in the Code.
Recommends redrafting of subsection 1.1.1 — 10(7A) to clarify that the intended scope is limited to caffeine as it may be interpreted that the presence of all substances listed in subsection 1.1.1 — 10(6) will be prohibited in guarana extract even though naturally occurring. For example, naturally occurring tannin in guarana extract may be interpreted as a non-compliance with the prohibition	NSWFA	FSANZ agrees. See section 2.3.3 of this report, and the amendment to subsection 1.1.1—7(A) which now refers just to caffeine as the substance being referred to by the subsection.

Issue raised	Submitter(s)	FSANZ response
of food additives (paragraph 1.1.1 — 10(6)(a)).		
Suggested a drafting change (a new note after this provision) to clarify meaning of guarana extract: **Note**: Although guarana naturally contains caffeine, guarana extract is treated as a prescribed caffeine product for regulatory purposes because: (a) it is typically added to foods in concentrated form specifically to increase caffeine content rather than for its traditional culinary use; and (b) caffeine concentrations in guarana extract products typically exceed those found in traditional caffeinated foods such as coffee, tea, cocoa and chocolate. This distinction ensures that concentrated caffeine sources added primarily for their stimulant properties are subject to appropriate labelling and limits, regardless of whether the original plant naturally contains caffeine.	SAH	FSANZ agrees. See section 2.3.2 of this report, and the definition of guarana extract.
Naturally occurring caffeine – coffee-containing beverages high in caffeine *At the consultation paper, the draft variation proposed to amend Standard 2.10.4 by adding section 2.10.4—3A to that Standard.* *The new section would set out the following labelling requirements for high caffeine coffee beverages:* *(a) declaration in the NIP of the average quantity of caffeine, expressed in milligrams, in a serving of the food and in a unit quantity of the food* *(b) advisory statements to the effect that the food is high in caffeine and not suitable for children under 15 years of age, or pregnant or breastfeeding women.* *For the purposes of the above, the draft variation would amend Standard 1.1.2 to include a definition of a high caffeine coffee beverage in section 1.1.2—3. The definition would provide that a high caffeine coffee beverage is a packaged beverage with a NIP that is a food for retail sale, contains coffee and no less than 200 mg caffeine per serving. The definition would state that formulated caffeinated beverages and formulated supplementary sports foods are not high caffeine coffee beverages.*		
AFGC supports proposed amendment, noting the proposed two-year transition period for implementation.	AFGC	FSANZ notes this support.
Supports advisory statements for high-caffeine coffee beverages.	DAFF	FSANZ notes this support.
Supports defining ‘high-caffeine’ beverages as ≥200 mg caffeine per serve and clear labelling and advisory statements, provided	CMA	FSANZ notes this support.

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they are practical and do not restrict innovation.		
Supports the new labelling requirements for high caffeine coffee beverages. Considers subparagraph 1.2.8—5(2)(a)(v) should not disqualify pre-packaged ready to drink black coffee products from being a high caffeine coffee beverage if all other conditions are met. The existing definition for 'coffee' in the Code may allow interpretation that black coffee beverages are captured as 'coffee', if no other food ingredients (such as milk or sugar) are added. Some parts of the Code use the term 'coffee' to mean coffee beverages, e.g. Schedule 15 lists 'coffee' under the category for 'non-alcoholic beverages and brewed soft drinks'; Schedule 18 lists 'coffee' with other beverages as permitted types of food for two processing aids. To avoid doubt, recommends clarifying that existing subparagraph 1.2.8—5(2)(a)(v) does not apply to pre-packaged coffee beverages.	NSWFA	FSANZ notes this support. Amendment of existing subparagraph 1.2.8—5(2)(a)(v) to exclude its application to pre-packaged coffee beverages is out of scope. FSANZ is not aware of evidence that black coffee products of the type described by the submitter are on the market.
Supports the intent of the proposed revisions to Standard 2.10.4 to reduce the risk of over consumption of caffeine particularly among sensitive sub-populations. For consistency, suggests updating subsection 1.1.2—3(2) to align with section 2.10.4—2 by inserting '; and' at the end of paragraph (c). Notes that some RTD coffees will require the proposed labelling and some will not. The inconsistency may confuse consumers particularly given the limited general understanding of the recommended daily intake of caffeine levels.	ABCL	FSANZ notes this support. The suggested amendment has been made to the approved draft variation. FSANZ acknowledges that some RTD coffees may be labelled with the caffeine content and advisory statements while others may not but has maintained the proposed approach. The advice that the product is 'high in caffeine' provides an explanation as to why it may appear on some products but not others. FSANZ considers the approach proportionate to the risk posed to consumers while balancing it with the impact of amending existing labels for lower caffeine products. Manufacturers can voluntarily label products that contain less than 200mg caffeine per serve with the caffeine content and advisory statements if, for example, they consider it would be beneficial to consumer understanding.

Issue raised	Submitter(s)	FSANZ response
Require a mandatory warning statement to the effect that high caffeine coffee beverages are not suitable for children under 18 years of age [i.e. change specified age limit from 15 to 18 years of age].	ECU	FSANZ has not changed the age from 15 years to 18 years in the advisory statement for high caffeine coffee beverages. The rate of clearance of caffeine in adolescents is comparable to that of adults, so caffeine intake up to 3 mg/kg bw as an acute dose is likely to be safe for this age group. There are only minor differences in body weight between adolescents (15-18 years in this context) and adults. A single acute dose of up to 210 mg is therefore not associated with adverse effects in adolescents aged between 15 and 18 years.
Supports advisory (preferably warning) statements for high-caffeine beverages (≥200 mg/serve) but recommends warning statements like FSSF – should explicitly caution children, adolescents, pregnant & breastfeeding women, and caffeine-sensitive individuals. Recommends lowering the threshold of caffeine content triggering the necessity of a warning statement given evidence of youth overexposure (references provided). Recommends standardised serving sizes for high coffee containing beverages, otherwise manufacturers will be able to adjust the serve size to suit the caffeine concentration. Recommends standardised serving sizes for all products containing significant quantities of caffeine to avoid the potential harm from misleading marketing of high-caffeine 'single serve' size packs.	PHAA	FSANZ notes this support. The advisory statement refers to children under 15 years of age for the reasons outlined in the response above. It also refers to pregnant and breastfeeding women. It does not refer to caffeine-sensitive individuals for the same reasons outlined in section 2.2.9.2 of the 2nd CFS in respect of FSSF. That is, FSANZ considers the likely knowledge of this population group about caffeine consumption would be sufficient to manage risks. A warning statement was not proposed because FSANZ considered it was not commensurate with the risk posed by these products. Consumers are generally aware that coffee beverages contain caffeine and are not suitable for children, adolescents, pregnant and breastfeeding women or other caffeine-sensitive individuals. The lower level of prescription associated with an advisory statement is proportionate with this higher level of consumer understanding compared to FSSF. Standardising serving sizes will not limit the amount of caffeine in a product. Compositional limits would achieve this objective, however they were not proposed for the reasons outlined in section 2.2.31

Issue raised	Submitter(s)	FSANZ response
		of the consultation paper. That is, it was not proportionate with the level of risk posed and would be challenging to enforce without labelling of the amount of caffeine present on all coffee beverages, regardless of the amount of caffeine they contain. Additionally, restrictions on the permissions to add caffeine to foods will also limit the amount of caffeine in food.
Supports labelling requirements for packaged coffee beverages. Recommends caffeine quantity be declared on all packaged coffee and tea beverages with a nutrition information panel, not just those with ≥200 mg caffeine per serve. This approach supports dietary guidelines, especially for pregnant individuals (limit caffeine to <200 mg/day). If this change is made, the heading of the provision should be changed to 'coffee beverage'. Points out that serving sizes can be manipulated. Can risk of manufacturers manipulating serving sizes be mitigated?	NZFS	FSANZ notes this support. The draft variation has not been amended to require caffeine content to be declared on all packaged coffee and tea beverages with a nutrition information panel. FSANZ considers the approach to require labelling of coffee beverages with a caffeine content of 200 mg caffeine per serving or more is proportionate to the risk posed by these products. Most consumers are aware that coffee and tea contain caffeine. Consumer education is important to support awareness of the risks associated with caffeine consumption, particularly for sensitive subpopulations such as pregnant women (see section 3 of this report for more on communication). See response to PHAA above regarding standardised serving sizes.
Per serving should be defined in the context of the provision: • Does 'serving' mean the manufacturer's declared serving size on the nutrition information panel? • Does it mean the entire container if sold as a single-serve package? • What if a product contains 180 mg per 250 mL (the labeled serving) but is sold in a 500 mL container (360 mg total)? Drafting options provided by submitter. Included suggestion of requiring the proposed labelling if the food contains no less than	SAH	A per serving basis is a common measure used in the Code, with a serving defined in Standard 1.1.2 as 'an amount of food which constitutes one normal serving when prepared according to manufacturers' directions or when the food requires no further preparation before consumption'. The intention is that the serving size is the serving size declared in the nutrition information panel (the average quantity of the food in a serving). If a product contains 180 mg per 250 mL serving but

Issue raised	Submitter(s)	FSANZ response
200 mg caffeine per: (i) serving of the food as declared in the nutrition information panel; or (ii) package, if the package is presented or commonly consumed as a single serve.		is sold in a 500 mL container (360 mg total), the new labelling requirements for high caffeine coffee beverages would not apply. As noted above, manufacturers have a responsibility to consider what would comprise a normal consumption amount of their product, and label accordingly. Regarding the suggestion in (ii), FSANZ considers it would be difficult from an enforcement perspective to identify whether a package is commonly consumed as a single serve, particularly if it is labelled as containing more than one serving. FSANZ has therefore not amended the draft variation as suggested by the submitter.
Recommend introducing mandatory caffeine labelling and serving size guidance for all products with added caffeine (ingredient declaration plus mg/serve where feasible, consistent with FCB practice and Canadian energy drink labelling).	MO	No changes have been made in response to this comment. Mandatory labelling relating to caffeine is required based on the risk posed by the product and its caffeine content. Regarding serving size guidance, see the response to PHAA about standardised serving sizes above.
Duplicate definitions, creates risk of inconsistencies – only one is needed, use a cross reference instead (subsection 1.1.2—3(2) and 2.10.4—2).	SAH	This is standard drafting practice in the Code and was endorsed by Food Ministers in Proposal P1025. Standard 1.1.2 is where definitions of terms used in the Code are set out (unless the contrary intention is expressed elsewhere in the Code). The definition in Standard 2.10.4 is in a note only, for reference purposes.
Request that any measures adopted, such as labelling requirements, align with existing requirements in Australia and New Zealand for declaring the presence of caffeine. Consistency will help avoid confusion for consumers and reduce unnecessary compliance burdens for industry.	SO	Consistency of labelling requirements has been achieved where applicable and appropriate, as outlined in P1056 consultation documents and this approval report.

Issue raised	Submitter(s)	FSANZ response
Support targeted improvements to labelling for products containing higher caffeine levels including coffee beverages greater than 200 mg per serving and FSSF and consider strengthened product labelling should complement not replace consumer education on safe consumption practices.	ARA/NRA	FSANZ notes this support. FSANZ agrees that strengthened product labelling should complement not replace consumer education.
In the heading above subsection 2.10.4 — 3A(2), add 'advisory statements' after 'Required', so that the heading reads 'Required advisory statements'.	NSWFA	FSANZ agrees. This amendment has been made to the draft variation.
In subsection 2.10.4—3A(1), recommends replacing 'caffeine' with 'caffeine in total, from any source', for consistency and to ensure for high caffeine coffee product containing coffee and other sources of caffeine, the required declaration in the NIP is for caffeine in total, from all sources present.	NSWFA	The approved draft variation has been amended to include 'from any source' but not 'in total'. FSANZ considers that the phrase 'average quantity of caffeine *in total'* could be confusing, because the definition of average quantity for the purposes of this requirement refers to the *average* of the amount of a substance for such foods from that producer or manufacturer.
Recommends adding a subsection similar to subsection 2.9.4—11(3) to require a consistent location in the NIP for the caffeine declaration for high caffeine coffee beverage and FSSF. Notes FCBs also subject to caffeine declaration in a NIP format unique to FCB, with the location not identical to that proposed for FSSF in subsection 2.9.4—11(3), but comparable as the row for caffeine is also below 'sodium'.	NSWFA	The approach in subsection 2.9.4—11(3) requires caffeine to be declared below the information about sodium and above any other nutrient or biologically active substance in the NIP. For a high caffeine coffee beverage, caffeine would need to be declared below sodium in the NIP in accordance with the prescribed format for a NIP in S12. It would not need to be above any other nutrient or biologically active substance in the NIP however a high caffeine coffee beverage is unlikely to have many, if any, other nutrients or biologically active substances in the NIP, unlike a FSSF which is likely to have a number. On the label of an FCB, the average quantity of caffeine must not be in the NIP but may be adjacent to the NIP and may be set out in the format in S12—5. It therefore may or may not be presented below

Issue raised	Submitter(s)	FSANZ response
		sodium and above any other nutrient or biologically active substance.
Labelling when caffeine is present from certain ingredients in FSSF *At the consultation paper, the draft variation proposed to amend section 2.9.4—2 to define caffeine for the purposes of subparagraphs 2.9.4—4(1)(iii) and (iv) and subsection 2.9.4—11(1). The amended section 2.9.4—2 would provide that caffeine for these purposes does not include caffeine from any of the following sources:* *(a) cocoa;* *(b) chocolate;* *(c) decaffeinated coffee containing no more than 1 g/kg of anhydrous caffeine on a dry basis;* *(d) decaffeinated tea containing no more than 4 g/kg of anhydrous caffeine on a dry basis;* *(e) decaffeinated instant coffee containing no more than 3 g/kg of anhydrous caffeine on a dry basis;* *(f) decaffeinated instant tea containing no more than 3 g/kg of anhydrous caffeine on a dry basis.*		
Supports proposed approach.	NZFSA	FSANZ notes this support.
Supports FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and decaffeinated coffee (meeting compositional limits) will be exempt from some caffeine-related labelling requirements. Agrees these ingredients do not pose a risk. This should not preclude these ingredients being included in the calculation for total caffeine in an FSSF. Agrees naturally occurring caffeine in FSSF from sources other than above (e.g. caffeinated tea or coffee or guarana) are a significant source of caffeine and will be subject to all caffeine-related labelling requirements for FSSF.	NSWFA	FSANZ notes this support. The approach requires these ingredients to be included in the calculation for total caffeine in a FSSF.
Supports exemptions only for caffeine from cocoa/chocolate/decaffeinated sources.	PHAA	FSANZ notes this support.
Supports exemptions for naturally occurring caffeine.	DAFF	FSANZ notes this support.
Not including coffee and tea creates inconsistency with labelling of general foods containing naturally occurring caffeine. Recommends amending section 2.9.4—2 to include coffee and tea in the list of	AFGC	Coffee and tea were not included in the exemption due to their higher caffeine content and therefore their potential to contribute more significant amounts

Issue raised	Submitter(s)	FSANZ response
exempt sources. Alternatively, introduce a minimum caffeine threshold for labelling requirements to avoid over-regulation. Consumer safety remains adequately controlled by measures that restrict caffeine from any source to 200 mg in a one-day quantity and limit the concentration.		of caffeine to a FSSF compared to chocolate etc. A threshold has not been developed because it is difficult to determine a scientifically valid technological or pharmacological basis for such a limit.
Supports exemptions from caffeine warnings for cocoa, chocolate, decaf coffee/tea; suggests extending exemptions to other low-caffeine ingredients.	CMA	FSANZ notes this support. FSANZ has not identified any other 'low-caffeine' ingredients it considers suitable for inclusion in the exemption. See above response regarding tea and coffee. Food additive (flavours) containing caffeine have only one permission (cola drinks). Any other coffee flavour cannot contain caffeine but can still contribute a coffee flavour.
Considers it confusing to apply a circular definition of caffeine in section 2.9.4—2. Recommends removing that and achieving the same intent by an additional clause under relevant sections of Standard 2.9.4. Recommends adding an exclusion clause to section 2.9.4—11 to the effect that FSSF containing caffeine only from certain sources (e.g. cocoa, chocolate) will not be subject to the requirement for caffeine content declaration in the NIP. Recommends amending the drafting to clarify FSSF containing caffeine only from certain sources (e.g. cocoa, chocolate) will be subject to the warning statement required in subparagraphs 2.9.4 — 4(1)(a)(iii), instead of the specific warning statement and advisory statement as proposed in subparagraphs 2.9.4 — 4(1)(a)(iv).	NSWFA	The draft variation has been amended as suggested by the NSWFA – see sections 2.9.4—4 and 2.9.4—11 of the approved draft variation.
Inconsistent definition of caffeine across standards creates ambiguity and confusion. Notes that a FSSF containing 150 mg caffeine from chocolate would be treated differently under different subsections. The amendment correctly recognises that FSSF containing only	SAH	FSANZ notes this support for the amendment. The submitter is correct that the 'special definition' of caffeine did not apply to the limits in paragraph 2.9.4—3(2)(c) and subsection 2.9.4—3(3). Regarding the comment about confusion due to the

Issue raised	Submitter(s)	FSANZ response
naturally occurring caffeine from traditional sources (chocolate, cocoa, decaffeinated tea/coffee) should not be subject to the same stringent requirements as FSSF with added caffeine. However, the execution creates confusion throughout Standard 2.9.4. Section 2.9.4—2 states the 'special definition' applies only 'in subparagraphs 2.9.4—4(1)(a)(iii) and (iv) and subsection 2.9.4—11(1).' This means maximum limits (Section 2.9.4—3(2)(c) and (3)): special definition does NOT apply. Example A FSSF containing 180 mg caffeine from chocolate, 50 mg caffeine from guarana extract, Total: 230 mg caffeine • Does NOT require warning statements (because definition excludes chocolate caffeine, leaving only 50 mg from guarana) • DOES violate the 200 mg total limit in Section 2.9.4—3(2)(c) (because 'from any source' includes chocolate) • Creates inconsistency: the product exceeds limits but requires no warnings.		execution, the draft variation has been amended – see sections 2.9.4—4, 2.9.4—11 and 2.9.4—12 of the approved draft variation. In the example provided: • the warning statement would apply as the food contains caffeine from a source other than cocoa, chocolate, decaffeinated tea or decaffeinated coffee (including instant versions) – there is no limit on the amount of caffeine required in the food for the warning statement to apply • the limit in paragraph 2.9.4—3(2)(c) of 200 mg caffeine in total, from any source, in a one-day quantity, applies.
Extending mandatory labelling to all foods with naturally occurring caffeine is not supported on the grounds of proportionality, regulatory efficiency and scientific necessity. Consumer research and history of consumption indicate that caffeine in coffee, tea and cocoa is safe. The public health benefit of mandating labelling for these foods is likely to be minimal relative to compliance burden on industry and regulators. A better approach would be to have clear quantitative declarations on products where coffee is added at variable and potentially high concentrations, including instant coffee, FCBs and sports supplements.	IS1	FSANZ did not propose extending mandatory labelling to all foods with naturally occurring caffeine but did propose an exemption from caffeine-related labelling requirements for FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and decaffeinated coffee. Quantitative declarations of caffeine will be required on certain FSSFs and coffee-containing beverages, similar to existing requirements for FCBs. See sections 2.3.5, 2.3.8.1 and 2.3.8.6 of this report.

Issue raised	Submitter(s)	FSANZ response
Labelling of individual portions in caffeine-containing FSSF *At the consultation paper, the draft variation proposed when an FSSF meets each of the criteria set out in the new section 2.9.4—12, the following would apply:* *(a) The FSSF's outer package must have an advisory statement to the effect that the food contains caffeine. This is the advisory statement required by subparagraph 2.9.4—4(1)(a)(iv)(A). Section 2.9.4—12 will require this statement appear on the outer package of the FSSF.* *(b) Each individual portion included within the packaging of the FSSF, and which meets the above criteria (i.e., in a solid or semi-solid form, not designed for individual sale, no further preparation required before consumption) must bear a label, with an advisory statement to the effect that the food contains caffeine, if it has a surface area of 30 cm2 or greater.*		
Supports additional labelling for FSSFs in single-serve portions.	DAFF	FSANZ notes this support.
Supports the new requirement	NSWFA	FSANZ notes this support.
Supports the amendment as it improves transparency for consumers.	AFGC	FSANZ notes this support.
Considers the proposed provision in subsection 1.2.1—8(3) has incorrect mention to subsection 2.10.4—3A(2), which is irrelevant to individual portion packs. Should the reference be 2.9.4—12(5)? If so, is the proposed paragraph 1.2.1—8(3)(b) necessary? The existing subparagraph 1.2.1—8(1)(y)(iv) already lists the required statements and other information for FSSF with the reference to Standard 2.9.4, under the heading 'General and additional requirements — retail sales' (i.e. subsection 1.2.1—8(1)). The reference to the whole Standard 2.9.4 here may already capture subsection 2.9.4—12(5). If specifically listing the requirement set out in subsection 2.9.4—12(5) under the heading 'Specific requirement — retail sales of food in individual portion packs' (i.e. subsection 1.2.1—8(3)), recommend using the same term 'individual portion packs' in the provisions in 2.9.4—12(5) for consistency with the term used in subsection 1.2.1—6(3).	NSWFA	The reference to subsection 2.10.4—3A(2) in 1.2.1—8(3) is intentional. The intention is to require high-caffeine coffee beverages in individual portion packs to be labelled with the advisory statements relating to caffeine. See section 2.3.5 of this report. The term 'individual portion pack' is not used in subsection 2.9.4—12(5) because the definition of individual portion pack in the Code is not appropriate for the requirements set out in that section. The term 'individual portion' is used so that the labelling requirement in subsection 2.9.4—12(5) applies only to individual portions referred to in subsection 2.9.4—12(1).
Request either:	IndS1	All FSSF must bear a label with the required statements and other information specified in

Issue raised	Submitter(s)	FSANZ response
• Clarification in the drafting for subsection 2.9.4—12(2) that both the warning statement and the advisory statement are required on the outer package of FSSF in a multi-pack (containing caffeine and required to be individually wrapped). • Removal of subsection 2.9.4—12(2) if it is duplicative of the general requirements already specified in subparagraph 2.9.4—4(1)(a)(iv), or • Clarification that only the advisory statement is required for individual portions ≥30cm2, consistent with the intent described in the consultation paper. The drafting currently refers only to the advisory statement and not the warning statement and could lead users to incorrectly assume that only the advisory statement is required on both the outer pack and the individual portions.		Standard 2.9.4 (see subsections 1.2.1—6(1) and 1.2.1—6(1)) which is legible at the point of retail sale. This includes but is not limited to applicable warning and advisory statements. FSANZ has therefore not clarified in the drafting that the warning statement and advisory statement are required on the outer package of the FSSF in a multi-pack. The requirement for the advisory statement (required by subparagraph 2.9.4—4(1)(a)(iv)(A)) to be on a label on the outer package of the FSSF is not duplicative because under subsection 1.2.1—6(2), if the food has more than 1 layer of packaging and subsection 1.2.1—6(1) requires it to bear a label, only 1 label is required. It was therefore included so that the advisory statement is required both on the outer package of the bulk FSSF and the inner portion. The only labelling requirement specified in the draft variation for the individual portion described in subsection 2.9.4—12(1) was for each individual portion with a surface area of 30 cm^2 or greater to bear a label with an advisory statement to the effect that the food contains caffeine. FSANZ has therefore not amended the drafting as requested by the submitter.
The advisory statement required by subparagraph 2.9.4—4(1)(a)(iv)(A) must be on a label on the outer package of the FSSF. This includes only the requirement for an advisory statement to the effect that the food contains caffeine. However, further clarity is required about whether the caffeine warning statement should also be included.	CMA	As outlined in the response above, all FSSF must bear a label with the required statements and other information specified in Standard 2.9.4 (see subsections 1.2.1—6(1) and 1.2.1—6(1)) which is legible at the point of retail sale. This includes but is not limited to applicable warning and advisory statements.
Recommends consistency in how to reference the advisory statement to the effect of ‘contains caffeine’. Subsection 2.9.4—12(2) refers to subparagraph 2.9.4—4(1)((a)(iv)(A) instead of	NSWFA	Subsection 2.9.4—12(2) refers to subparagraph 2.9.4—4(1)((a)(iv)(A) instead of directly mentioning the content of the advisory statement required by

Issue raised	Submitter(s)	FSANZ response
directly mentioning the content of the advisory statement, whereas subsection 2.9.4—12(5) describes the content of the advisory statement. Requests clarification in the Approval report that this requirement will apply to all FSSF, including FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and decaffeinated coffee.		that subparagraph because the purpose of subsection 2.9.4—12(2) is to specify where the advisory statement must appear, not what it must contain. Subparagraph 2.9.4—4(1)((a)(iv)(A) deals with the content. Subsection 2.9.4—12(5) deals with a specific situation / product and prescribes the advisory statement for an individual portion *included* in the FSSF (sold in packaging that includes), and where it must appear - on the individual portion. The intention of subclause 2.9.4—12(2) and 2.9.4—12(5) is that the advisory statements do not apply if the FSSF contains caffeine only from chocolate, cocoa, decaffeinated tea and decaffeinated coffee. The draft variation proposed in the consultation paper has been amended to clarify this.
Generally supports proposed advisory and warning requirements for FSSF. Recommends mandatory front-of-pack warning statements for all FSSF. Supports labelling both inner and outer packaging of multipacks; but recommends no exemptions for individual sachets or portions. Advisory and risk statements should be on both the inner and outer packaging of multipack FSSF, regardless of whether they are ready to consume or require further preparation.	PHAA	FSANZ notes this support. FSANZ is maintaining the approach in the consultation paper to not require the advisory statement and warning statements on individual portion labels of FSSF liquids and powders, for the reasons provided in section 2.3.2 of the consultation paper and section 2.3.8.5 of this report. Requirements for warning statements and labelling of inner portions for FSSF more broadly will be considered under Proposal P1010.
Recommends that all individually packaged caffeine-containing FSSF in multipacks should have a ‘contains caffeine’ statement, regardless of packaging size. Notes safety risks if small, individually packaged items are unlabelled, especially for vulnerable populations like children. Suggest requiring a ‘contains caffeine’ declaration at a minimum (as mentioned above, regardless of packaging size), but preferably the	NZFS	FSANZ is maintaining the approach in the CP to not require the advisory statement and warning statements on individual portion labels of FSSF liquids and powders, for the reasons provided in section 2.3.2 of the CP and section 2.3.8.5 of this report. The Code requires individual portion packs with a

Issue raised	Submitter(s)	FSANZ response
advisory statements described in the proposed subsection 2.9.4—4(1)(a)(iv) and any other required advisory statements (e.g. allergens). This is because when a 'contains caffeine' advisory statement is present, consumers may consider this to be a complete list of any required advisory statements.		surface area of 30cm^2 or greater to display warning statements and allergen declarations in accordance with sections 1.2.3—3 and 1.2.3—4. The requirements to display the advisory statement 'contains caffeine' on certain individual portions of FSSF with a surface area of 30 cm^2 is consistent with and in addition to these requirements.
While a warning statement above 200 mg of total caffeine for multipacks of FSSF may be supportable, note that small solid or semi-solid individual portions (e.g. bars, chewables, dissolvable strips) are limited to 200 mg of caffeine and under, therefore the proposed warning statement would not apply. The proposal is contradictory or confusing in this respect.	CMA	The proposed approach in the consultation paper for labelling of individual portions within a multi-pack was for an advisory statement rather than a warning statement. The intent is that the 200 mg caffeine, in total, from any source, specified in paragraph 2.9.4—12(1)(a) applies to the entirety of the multi-pack containing individual portions of FSSF, not to the individual portions themselves. The requirement for the advisory statement therefore applies both to the outer package of the multi-pack and the individual portions, if the conditions in subsection 2.9.4—12(1) are met. A warning statement would be required on the multipack itself regardless of the caffeine content (unless the caffeine is only from chocolate, cocoa, decaffeinated tea or decaffeinated coffee), as outlined in section 2.3.8.4 of this report.
Transition period *At the 2nd CFS (section 3.1), FSANZ proposed 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.* *FSANZ maintained this approach at the consultation paper.*		
Recommend a four-year transition period at a minimum. Given amendments are likely to impact products in market, a multi-year transition is required. If FSANZ progresses with the proposed	SNZ	The prohibition on adding guarana extract to food (including alcohol) is subject to the definition of 'guarana extract' to be included in subsection

Issue raised	Submitter(s)	FSANZ response
prohibition on guarana in alcohol beverages, a minimum transition period of four years is provided.		1.1.2—3(2). This allows the use of guarana, and guarana extracts that do not exceed the concentration limit for caffeine listed in that definition. The ability to mix compliant foods together has not changed under this proposal. Taken together, the impact on existing products may not be to the extent the industry has indicated (noting that the compositional data regarding the source of caffeine in impacted products was not provided by submitters – meaning FSANZ cannot determine if the products would be consistent with the new requirements or not). After providing further clarification on the compositional parameters for guarana extract in the draft variation (see Item [6], Attachment A), FSANZ considers an extension to the transition period is not needed as the regulatory impact of the prohibition is expected to be limited.
Amendments should include a four year transition period to allow for impact on products in the market.	Lion	See above response.
Does not support the proposed two-year transition period for compliance, recommending a three-year period to allow for manufacturing, packaging, and supply chain adjustments.	ABCL	The transition period will remain at 2 years. See section 5 of this report for FSANZ's rationale.
Does not support the proposed transition period for implementing new regulations. The Council recommends a 3-year transition period from gazettal to allow for manufacturing planning, packaging changes, and supply chain turnover.	NZBC	See above response.

Issue raised	Submitter(s)	FSANZ response
Recommend a phased implementation period of 18-24 months aligned with standard packaging refresh cycles together with clear regulatory guidance from FSANZ and access to compliance tools.	ARA/NRA	See above response.
CMA requests transition period align with P1010 finalization to avoid costly, fragmented label changes.	CMA	See above response. FSANZ has not aligned the transition period with that for P1010 because the transition period for P1010 is unknown at this stage and this approach could unreasonably delay the implementation of amendments to the Code resulting from P1056.
Other comments out of scope of the consultation paper *Section 2 of the consultation paper noted the purpose was to consult only on the proposed new changes to the draft variation.* *All other unchanged aspects of the draft variation were consulted on at the 2nd CFS and were out of scope for the consultation.* *The following submitter comments were not within scope of the proposed revisions to the draft variation in the consultation paper. Where out of scope issues raised were also raised in comments to the 2nd CFS, responses to these issues are included in table 2, Appendix 1 of the Approval Report.*		
Permission-based system for managing caffeine is seen as overly complex, manufacturers would face significant compliance obligations, needing to navigate permissions, definitions, and exemptions (e.g., “naturally occurring” caffeine, FCB, FSSF). FSANZ’s own risk assessment shows most consumers remain within safe daily limits; exceedances are mainly from tea and coffee, not added caffeine and international regulators (EFSA, FDA, Health Canada) manage caffeine risk through labelling and education, not blanket prohibitions. Recommend retain the 1 and 5% concentration limits, but manage other risks via mandatory labelling and education.	MO	The FSANZ risk assessment and submissions from the 1st and 2nd CFS identified areas relating to caffeine in food that required risk management that were not currently being addressed by the 1 and 5% concentration limits in food for retail sale (see table A of the 2nd CFS, table 2, Appendix 1 of this report and section 2.1 of the 2nd CFS) . FSANZ’s regulatory approach was proposed at the 1st CFS and well supported by submitters. Many submitters (both industry and jurisdictions) supported the approach citing increased regulatory clarity. In response to the risk assessment and submitter feedback, FSANZ’s approach has been to prohibit unless permitted and therefore the 1% and 5% concentration limits are no longer required.

Issue raised	Submitter(s)	FSANZ response
Considers a risk in solid and semi solid FSSF when caffeine is present in high concentrations. Current proposed provisions only apply to powdered or liquid forms of FSSF. It's unclear why these forms of FSSF were excluded (especially given they were included in the risk assessment and drafting for P1054). Forms such as pastilles, gums and gummies may still present a risk of over consumption of caffeine. FSANZ should consider amending paragraph 2.9.4—3(3)(a) to also include solid and semi-solid foods and provide clarity for FSSF that are more than one form (e.g. capsules containing a liquid or powder)	QLDH	This issue was raised previously by submitters in response to the 2nd CFS and considered by FSANZ. FSANZ's response to this submitter is in Table 2, Appendix 1 of this report under the heading 'Packaging of solid or semi-solid caffeine-containing FSSF in a multi-pack'. In summary, FSANZ is requiring individual packaging requirements of these forms of FSSF. Certain sports supplements are therapeutic goods for the purposes of that Act (and therefore not a food).
Evidence supports safe use of caffeine above 200 mg for athletes; CMA requests flexibility for higher doses and health claims. At a minimum, suggests permitted statement to the effect that athletes may use higher levels calculated against all sources of 3-6mg/kg bodyweight, for the specific goal of enhancing sports performance.	CMA	This issue was raised previously by submitters in response to the 2nd CFS and considered by FSANZ. FSANZ's response to this submitter is in Table 2, Appendix 1 of this report under the heading 'New express permission for caffeine in FSSF'. In summary, the one-day quantity of caffeine in FSSF is limited to 200 mg, as determined by FSANZ's safety assessment.
In submitter's view, addition of caffeine to FSSF is not in alignment with Ministerial Policy Guideline on caffeine regulation.	ECU	This issue was raised previously by submitters in response to the 2nd CFS and considered by FSANZ. FSANZ's response to this submitter is in Table 3, Appendix 1 of this report under the heading 'Other'. In summary, 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 4.3 of this report).
200 mg caffeine per one-day quantity for FSSF is unnecessarily restrictive. EFSA and FSANZ both recognise a safe intake of up to 400 mg/day for healthy adults. Scientific evidence supports caffeine's performance benefits at doses of 3–6 mg/kg body weight. Sports foods are not a major contributor to caffeine intake among	MO	This issue was raised previously by submitters in response to the 2nd CFS and considered by FSANZ. FSANZ's response is in Table 2, Appendix 1 of this report under the heading 'New express permission for caffeine in FSSF'. In summary, the one-day quantity of caffeine in FSSF is limited to 200 mg, as determined by FSANZ's safety

Issue raised	Submitter(s)	FSANZ response
vulnerable groups. Recommend increasing the limit to 400 mg, with mandatory cautionary labelling and consumer education.		assessment.
Support 200 mg permission and one-day quantity in FSSF to contain caffeine from any source.	IndS1	FSANZ notes this support.
Recommends the advisory statements on formulated caffeinated beverages are upgraded to warning statements for consistency between all foods containing caffeine in quantities greater than or equal to 200 mg per serve.	PHAA	The new approach for high caffeine coffee beverages requires an advisory statement, not a warning statement, consistent with the requirement for FCBs.
Request discussion in the Approval Report as to whether the proposed drafting includes caffeine pouches which could be a potential novel food.	QLDH	This issue was raised previously by submitters in response to the 2nd CFS and considered by FSANZ. FSANZ's response to this submitter is in Table 2, Appendix 1 of this report under the heading 'Packaging of solid or semi-solid caffeine-containing FSSF in a multi-pack'. In summary, whether chewing gum and caffeine pouches would be permitted for sale as FSSF is a compliance and enforcement matter for food regulators.
Support the development of a coordinated education campaign to reinforce safe consumption practices and increase understanding of cumulative caffeine intake.	ARA/NRA	More details on education are provided in section 3.2 of this Report. FSANZ will consider the best way to approach consumer education on caffeine in the food supply and anticipates working cooperatively with food regulation system partners to ensure consistency of information and to maximise the effectiveness of available resources.
Notes the importance of consumer education to support awareness of caffeine-related risks and recommends clear communication strategies to help consumers understand safe caffeine intake and interpret product labelling. Notes that most overconsumption occurs via tea and coffee, not specialty beverages.	ABCL	FSANZ notes this comment. See response above.

Issue raised	Submitter(s)	FSANZ response
FSANZ should develop a targeted communication strategy using multiple channels (e.g., social media) to complement labelling requirements and should leverage existing consumer information resources to educate on safe caffeine intake.	AFGC	FSANZ notes this comment. See response above.
Recommend consumer education campaigns for vulnerable groups, consistent with FSANZ's risk communication function and international public health practice.	MO	More details on education are provided in section 3.2 of this Report.
Emphasises the need for effective education on the safe use of caffeine, especially for sportspeople and recommend that FSANZ and relevant jurisdictions update education materials and communication plans alongside regulatory changes.	NZFGC	FSANZ notes this comment. See above responses on consumer education.
Supports the development of guidance documents to assist with implementing new caffeine provisions. Offered to assist FSANZ and/or the Implementation Subcommittee for Food Regulation in developing guidance.	NZFS	FSANZ notes this support.
The RIS does not cover alcohol beverages within its scope. In order to identify the economic impacts on manufacturers a full RIS should be undertaken which details the impact on all sectors.	Lion	At the consultation paper FSANZ indicated that a small number of products are expected to be impacted by the prohibition of guarana extract (except where expressly permitted to be added). FSANZ did not receive alternative estimates to quantify this impact.
Notes that relabelling and reformulation costs are likely underestimated.	NZBC	The transition period will remain at 2 years. See section 5 of the Approval Report for FSANZ's rationale.
Notes that relabelling costs are likely underestimated and have increased since the last survey. Supports FSANZ's ongoing review of its cost model to ensure accurate future assessments.	ABCL	See above response. Support is noted for the update of the existing label change cost model.
FSANZ underestimates reformulation and relabelling costs,	CMA	P1056 is regulating the addition of caffeine to food.

Issue raised	Submitter(s)	FSANZ response
especially for Small and Medium Enterprises may be more substantial for certain businesses. Reformulation to remove added caffeine—or to manage caffeine contributions from botanical extracts—may necessitate additional resources, such as technical development work, stability testing, and potentially the sourcing of new ingredient inputs, which could lead to additional compliance costs beyond those captured in FSANZ's modelling. There are also concerns that the requirement to remove added caffeine sources—including scenarios where guarana extract is deemed an added caffeine ingredient—could disproportionately affect niche or innovative products. Instead of automatically deeming these products novel food ingredients, there should be the option to include them provided the product has a limit on the amount of total caffeine.		Whether caffeine is from a natural source such as guarana extract or chemically synthesised, the regulation is still for the same molecule, caffeine. Guarana extract has not been categorised as a novel food.
Notes FSANZ's acknowledgement that some or all of these costs may ultimately be passed on to consumers, cumulative regulatory changes—particularly when combined with supply chain pressures, ingredient inflation and packaging cost escalations—may contribute to higher retail prices and reduced category diversity.	CMA	The DRIS continues to note that any cost experienced by industry may be passed on in part or in full to consumers.
Believes FSANZ's cost estimates for label changes are outdated and too low. Actual costs are significantly higher, and additional costs for discontinuing or reformulating non-compliant products are not included. Recommends re-engaging with industry to ensure cost modelling figures are accurate.	NZFGC	Throughout the proposal FSANZ encouraged stakeholders to provide data which would enable the total cost to be estimated. Limited data was received. The assessment was based on the best available information at the time the decision was made to prepare the amendments.
FSANZ to consider public health and government costs, not just industry costs, in regulatory impact assessments.	PHAA	Public health and government costs have been considered qualitatively. The assessment was based on the best available information at the time the decision was made to prepare the amendments. That included submissions received from stakeholders in response to the 1st and 2nd CFS and the additional consultation paper.

Issue raised	Submitter(s)	FSANZ response
A thorough Regulatory Impact Statement is required due to short-comings in the current cost-benefit analysis. A full RIS should detail the impact on all sectors and presents a more honest appraisal of the absence of benefits from the proposed prohibition of guarana in alcohol beverages.	SNZ	The assessment was based on the best available information at the time the decision was made to prepare the amendments. That included submissions received from stakeholders in response to the 1st and 2nd CFS and additional consultation paper. At the consultation paper FSANZ indicated that a small number of products are expected to be impacted by the prohibition of guarana extract (except where expressly permitted to be added). FSANZ did not receive alternative estimates to quantify this impact.
Require mandatory warning statement for FCBs and for FSSF that they are 'not suitable for children aged under 18 years,' [i.e. changed from no specified age limit to 18 years of age and changed to mandatory warning statement].	ECU	This issue was raised previously by submitters in response to the 2nd CFS and considered by FSANZ. FSANZ's response to this submitter is in Table 3, Appendix 1 this Report under the heading 'Formulated caffeinated beverages'. In summary, the rate of clearance of caffeine in adolescents is comparable to that of adults, so caffeine intake up to 3 mg/kg bw as an acute dose is likely to be safe for this age group
Suggest the retail sale of FCBs and FSSF and beverages and other foods with added caffeine whether added as a substance or a concentrated extract or proprietary blends from 'naturally sources' should be prohibited to people under the age of 18 years in Australia and New Zealand (evidence provided to the 2nd CFS).	ECU	This issue for FCBs was raised in response to the 2nd CFS and considered by FSANZ. FSANZ's response to the submissions is in Table 3, Appendix 1 of this report. FSANZ has not identified a risk that would necessitate this approach. This is based on the outcome of FSANZ's safety assessment (see section 2.2 of this Report), the existing risk management measures for FCBs and the approach for FSSF as outlined in this report.
Food permitted to add caffeine (added as a substance or a concentrated extract, including proprietary ingredients) should	ECU	FSANZ has applied specific labelling requirements to certain foods based on the level of risk posed by

Issue raised	Submitter(s)	FSANZ response
require a mandatory warning statement to the effect that these products are not suitable for children aged under 18 years, a statement that the food contains caffeine, and the caffeine quantity included in the nutritional information panel.		the caffeine content and taking into account the restrictions on the permission to add caffeine to food. Broader labelling requirements applying to any food permitted to contain caffeine are therefore not considered necessary.
Considers consumers are unlikely aware of the presence of caffeine in non-traditional foods (that are not considered novel) e.g. coffee berry (cherry) drink – from the Advisory Committee Novel Foods' (ACNF) register. Consumers should be informed that these foods contain caffeine, and recommends the same advisory statement required in S9—2 should be required. Inconsistent with labelling required for cola type drinks which typically contain lower levels of caffeine.	NSWFA	As noted above, FSANZ has applied specific labelling requirements to certain foods based on the level of risk posed by the caffeine content. No safety concerns were identified with coffee cherry ready-to-drink products when considered by the ACNF in 2018. FSANZ is not aware of any data that has subsequently demonstrated safety concerns associated with the caffeine content of this product.
It is unclear how capsules, which may contain powders or liquids within them, would be regulated by 2.9.4—12 (1)(c)(i) because it is uncertain if they are solid or semi-solid forms. Similarly, gels appear to have been excluded. It is also not clear why multipack powders are excluded. If such forms of FSSF are to be permitted, considerations should be given to excluding 2.9.4—12 (1)(c)(i) from the drafting to capture all forms for FSSF products.	QLDH	The issues of capsules and powders were raised by submitters in response to the 2nd CFS and considered by FSANZ. FSANZ's response to the submissions is in Table 2, Appendix 1 of this Report. Gels are intended to be captured in the solid and semi-solid forms category and therefore would be risk managed through the individual packaging requirement set out in 2.9.4—12.
For FSSF, considers there is a regulatory gap with no caffeine limit specified for other common formats, including: 1. Semi-solid forms (gels, pastes, spreads) — the very formats addressed in Section 2.9.4—12 2. Solid forms (bars, tablets, chewables, capsules) 3. Dissolving strips or films 4. Emulsions or suspensions 5. Dual-phase products (e.g., powder + liquid in a shaker). Example 1	SAH	Paragraph 2.9.4—3(1)(d) sets out that a FSSF may contain caffeine and paragraph 2.9.4—3(2)(c) sets out that FSSF must not contain, in a one-day quantity, more than 200 mg caffeine, in total from any source. This permission and compositional limit applies to all FSSF, regardless of the format. Example 1: Gels are intended to be captured in the solid and semi-solid forms category and therefore would be risk managed through the individual packaging requirement set out in section 2.9.4—12. Concentration limits were not deemed to be an

Issue raised	Submitter(s)	FSANZ response
1. A sports gel containing 8% caffeine would be unregulated under Section 2.9.4—3(3) despite presenting identical or greater consumer risk than a powder at 5%. 2. Section 2.9.4—12 addresses multipacks of solid/semi-solid portions but Section 2.9.4—3(3) provides no concentration limits for these formats, creating a regulatory gap. 3. Manufacturers could avoid concentration limits by formulating products in unspecified formats. 4. Enforcement officers have no clear guidance on how to classify edge cases (e.g., "Is a thick gel considered liquid or semi-solid?"). 5. Innovation in product formats creates regulatory uncertainty. Example 2 A manufacturer produces a sports nutrition "chewable cube" in solid form containing 7% caffeine and sold in a multipack. Each individual portion is 30g containing 2,100 mg of caffeine (7% of 30g). Under current drafting: • Section 2.9.4—12 would prohibit this (individual portions exceed 200 mg) • But Section 2.9.4—3(3) has no concentration limit for solid forms • The interaction between per-portion limits and concentration limits is unclear. Drafting options provided by submitter.		appropriate risk management measure for solid and semi-solid FSSF for the reasons set out in section 2.2.4.2 of the 2nd CFS. Instead, these products are risk managed through a one-day quantity permission and individual packaging and labelling requirements. FSSF in liquid and powder form are subject to concentration limits of 1% and 5% respectively. Guidance is provided to enforcement officers and others through the example at subsection 2.9.4—12(1). Example 2: The product described in example 2 would not be permitted as an FSSF due to its total amount of caffeine, according to subsection 2.9.4—3(2)(c). If the product contained 200 mg of caffeine or less, it would be permitted as an FSSF however no concentration limits would apply as these apply to liquids and powders only. Instead, if the product met the requirements in section 2.9.4—12 it may require individual packaging of portions.
Considers the interaction of the requirements for multipacks with other FSSF requirements requires clarification. Specific questions: 1. Does Section 2.9.4—12(4) (individual portions must not exceed 200 mg) operate as an additional limit beyond Section 2.9.4—	SAH	1. Subsection 2.9.4—3(2)(c) is a one-day quantity maximum amount of caffeine; it is not related to the number or size of serves. Section 2.9.4—12(4) is a per individual portion maximum, regardless of how many serves are in the individually packaged portion.

Issue raised	Submitter(s)	FSANZ response
3(2)(c) (200 mg per serving), or is it intended to clarify that for multipacks, each portion is considered a "serving"? 2. If Section 2.9.4—12 applies to a multipack, do the concentration limits in Section 2.9.4—3(3) still apply? Currently, only powders and liquids have limits, but multipacks under Section 2.9.4—12 are 'solid or semi-solid form.' 3. Section 2.9.4—12(1)(c) applies to portions that 'do not require further preparation before consumption' — does this mean portions requiring mixing with water (common for powder sachets in multipacks) are excluded? Suggested clarifying notes to Section 2.9.4—12: Note 1: Each individual portion in a multipack is treated as a serving for the purposes of Section 2.9.4—3(2)(c). Note 2: The concentration limits in subsection 2.9.4—3(3) apply to the formulated supplementary sports food before packaging into individual portions. Note 3: "Do not require further preparation" means the portion can be consumed as packaged without addition of liquid or other ingredients, even if dilution or mixing is optional or recommended.		2. Because of differences in the types of FSSF products the new caffeine permission will apply to, different risk management approaches have necessarily been implemented. Concentration limits apply to powders and liquids for the reasons set out in section 2.3.7 of this Report and section 2.2.4 of the 2nd CFS. The individual packaging requirement applies to solid and semi-solid ready to consume individual portions in a multi-pack for the reasons set out in section 2.3.7 of this Report and section 2.2.4 of the 2nd CFS. 3. Section 2.9.4—12 does not apply to portions requiring mixing with water. Powders are not included in the individual packaging requirement in section 2.9.4—12. Instead they are managed through the 5% concentration requirement set out in subsection 2.9.4—12(4). Response to clarifying notes: Note 1 – This note is not required. The requirement at section 2.9.4—12 does not specify how many serves can or should be included in the individually packaged portions. The requirement does specify that individually packaged portion cannot contain more than the one-day quantity of caffeine i.e. 200 mg. A serving is not a specific amount and could vary according to manufacturer. Note 2 – This note is not required. These products to which subsection 2.9.4—3(3) applies may not be individually packaged. Regardless, the concentration would be the same regardless of what size packet the product was in or how many portions there were. Note 3 – This note is not required. If dilution is recommended, then the individual packaging requirement does not apply. If mixing is optional

Issue raised	Submitter(s)	FSANZ response
		(rather than recommended) the requirement cannot control how someone chooses to consume a product when they do something different to the instructions provided.
Drafting should provide clarity in regard to chewing gum presented as a FSSF. There are chewing gum products containing caffeine currently available for purchase that advertise they assist sports training. Some contain 100mg caffeine per piece but could potentially be formulated with higher levels.	QLDH	This issue was raised previously by submitters in response to the 2nd CFS and considered by FSANZ. FSANZ's response to this submitter is in Table 2, Appendix 1 of this Report under the heading 'Packaging of solid or semi-solid caffeine-containing FSSF in a multi-pack' In summary, whether chewing gum and caffeine pouches would be permitted for sale as FSSF is a compliance and enforcement matter for food regulators. If deemed a FSSF, such products would need to meet the composition and labelling requirements of FSSF including use of the prescribed name.
FSANZ should provide clarity in the drafting on maximum levels of caffeine in capsules and tablets if presented as FSSF (rather than therapeutic goods). It is unclear to how the proposed requirements for sections 2.9.4—3 and 2.9.4—12 would apply to these forms of FSSF.	QLDH	This issue was raised previously by submitters in response to the 2nd CFS and considered by FSANZ. FSANZ's response to this submitter is in Table 2, Appendix 1 of this Report under the heading 'New express permission for caffeine in FSSF' In summary, the TGA has declared under section 7 of the TG Act that certain sports supplements are therapeutic goods for the purposes of that Act (and therefore not a food). The declaration means that sports supplements will be regulated by the TGA as therapeutic goods if they are presented in the medicinal dosage of a pill, tablet or capsule or their ingredients meet the criteria of being higher risk to consumers. See section 1.4.2 of this Report for further information.

Issue raised	Submitter(s)	FSANZ response
Acknowledges further research concerning caffeine consumption in vulnerable population groups is warranted. Given our research to date on energy drinks and young people, ECU would be willing to undertake further research on caffeine and vulnerable population groups subject to the provision of funding.	ECU	FSANZ notes this comment.
Strong scientific evidence supports claims for endurance, alertness, and performance.	CMA	This issue is out-of-scope of this proposal. FSANZ will consider claims for FSSF under Proposal P1010.
Recommend allowing a pre-approved general level health claim regarding caffeine's beneficial effect on sports performance for FSSFs and challenges the scientific basis for a fixed 200 mg caffeine limit, noting that higher doses are supported by research for sports performance, especially for heavier athletes. Recommends reconsideration of the 200 mg limit for all product categories, particularly for sports performance products.	NZFGC	These issues were raised by submitters in response to the 2nd CFS and considered by FSANZ. FSANZ's response to the submissions is in Table 2, Appendix 1 of this Report under the heading 'New express permission for caffeine in FSSF'. In summary, permission for health claims about caffeine should be reviewed in the broader context of P1010 and the one-day quantity of caffeine in FSSF is limited to 200 mg, as determined by FSANZ's safety assessment.
After finalisation of P1056, the department will need to consult with FSANZ on a review of the imported food risk advice on pure and highly concentrated caffeine products.	DAFF	FSANZ notes this comment.
Support individual wrapping requirement for FSSF in a multi-pack that contain more than 200 mg caffeine in total.	IndS1	FSANZ notes this support.
Support intent to reduce inadvertent caffeine consumption by children but suggest permitting child-resistant blister packaging as an alternative to individual wrapping for small FSSF portions. Where child-resistant packaging is used, individual advisory statements are unnecessary and disproportionate. Recommend amending draft to exempt individually packaged portions from advisory labelling if child-resistant closures are used.	MO	The form of individual packaging is not prescribed under paragraph 2.9.4—12(2) as requirements may vary depending on product size and format. Regardless of form, the packaging helps limit total caffeine exposure for all consumers. There is nothing in the requirement to prevent a manufacturer from utilising blister packaging or child-resistant closures. While the advisory statement is intended to reduce

Issue raised	Submitter(s)	FSANZ response
		the risk of inadvertent consumption of caffeinated products by sensitive subpopulations, including children, it alerts all consumers to the presence of caffeine. FSANZ has therefore not provided an exemption from the requirement for an advisory statement if child-resistant closures are used. Note the advisory statement does not apply if the surface area is less than 30 cm^2.
The proposed amendments relating to individual wrapping in section 2.9.4—12 are not an effective risk reduction strategy to protect people, especially younger people from overconsumption of caffeine. Small individual portions, especially those that resemble confectionary, may present a risk to children. Separate packaging could mean a range of things (including easy to unwrap paper or foil to blister packaging). Further clarification on the forms of packaging requirements may be needed. FSANZ should consider the potential use of dispensers to deliver individual portions.	QLDH	The issue raised by the submitter that individual wrapping is not an effective risk reduction strategy was raised by submitters in response to the 2nd CFS and considered by FSANZ. FSANZ's response to the submissions is in Table 2, Appendix 1 of this Report.
Recommend category-specific maximums for high-risk products (e.g., energy drinks, sports supplements), aligned with international standards where the risk is higher – aligning with Health Canada's <180 mg/serving and existing Standard 2.6.4 labelling architecture for FCBs.	MO	Category specific maximums on the amount of caffeine permitted in FCBs (energy drinks) do exist and will be applied to FSSFs as outlined in this Report. FSANZ has also developed other measures to manage the risk from caffeine for the reasons stated in this report.
Recommends FSANZ undertake further investigation on legibility issues noting FSANZ's recent work on the NIP which identified legibility as an issue that may affect consumer understanding. There is no font size requirement for advisory statements. Whilst noting legibility requirements are out of scope of this proposal, it is important to make advisory statements about caffeine easily available to all consumers including vulnerable populations.	NSWFA	FSANZ notes this comment. The legibility of advisory statements is out of scope for P1056.
Raised conflict with NZ Supplemented Food Standard; recommends coordination and exemptions for supplemented foods.	CMA	The operation of the NZ SFS and the TTMRA are outside of FSANZ's remit and out of scope for P1056.

Issue raised	Submitter(s)	FSANZ response
		Sections 1.4.3 and 2.4.1.3 of the 2nd CFS provided a summary of how the proposed amendments may interact with New Zealand standards. NZFS has advised that paragraph 1.1.1—10(5)(g) of the Code applies to supplemented foods in NZ and that NZFS are reviewing the implications of regulatory measures proposed by this proposal for the caffeine provisions in the NZ SFS.
Proposed Code amendments may conflict with New Zealand's Supplemented Food Standard 2016, particularly around 'prescribed caffeine product'. Urges engagement between Australia and New Zealand governments, to prevent regulatory gaps and ensure non-traditional caffeine sources are properly classified.	NSWFA	See response above.
Some members manufacture under the Supplemented Foods Standard (2016), which allows caffeine for purposes other than as a food additive. Concern that proposed amendments would introduce a general prohibition on adding caffeine to retail foods (paragraph 1.1.1—10(6)(k) which would automatically apply to Supplemented Foods, creating regulatory misalignment and confusion. Such changes could impact export goods produced under the Supplemented Food Standard and require further amendments to that Standard.	NZBC	See response above.
Raised that the proposed changes will apply to Supplemented Foods, which under New Zealand's Supplemented Food Standard which can contain added caffeine without a prescribed upper limit. Significant concern that the amended paragraph 1.1.1—10(5)(g) and the newly added paragraph 1.1.1—10(6)(k) will apply without modification to Supplemented Foods, when the Supplemented Food Standard (Section 1.9) specifically permits the addition of caffeine. The proposed Code changes would impose a 200 mg/day limit which could make many products non-compliant and create	NZFGC	See response above.

Issue raised	Submitter(s)	FSANZ response
regulatory uncertainty and requires the NZMPI to amend the Supplemented Food Standard to ensure the proposed changes in clause 1.1.1—10 do not apply to Supplemented Foods. Recommends FSANZ coordinates with MPI to ensure Supplemented Foods are explicitly exempted under the revised Code.		
Recommends FSANZ address the risk of importing highly concentrated caffeinated products via TTMRA.	PHAA	See response above. Also see section 1.4.3 and 2.5.1.3 of the 2nd CFS for further information.
P1056 captures foods and beverages where caffeine is incidental and has not been identified as posing any health risk. It expands the scope of P1054 well beyond its original purpose which was to address the acute toxicity risks associated with pure and highly concentrated caffeine.	Lion	P1054 amendment was an interim and urgent measure following its review of pure and highly concentrated caffeine products which found these products pose an immediate and acute risk to Australian consumers and, as such, there was a need to act to protect public health and safety. The FSANZ P1056 risk assessment and submissions from the 1st and 2nd CFS identified risks relating to caffeine in food that were not currently being addressed by the 1 and 5% concentration limits in food for retail sale (see table A of the 2nd CFS, table 2, Appendix 1 of this Report and section 2.1 of the 2nd CFS). FSANZ's regulatory approach was proposed at the 1st CFS and well supported by submitters. Many submitters (both industry and jurisdictions) supported the approach citing increased regulatory clarity.
Sought clarification if subparagraph 2.9.4—3(1)(c)(ii)(d) relates to total caffeine.	SA Health	Subparagraph 2.9.4—3(1)(c)(ii)(d) relates to the permission to add caffeine to a FSSF. It does not include the condition of how much caffeine is permitted therefore it is not necessary to specify here that it is total caffeine. Instead, subsection 2.9.4—3(2)(c) specifies the amount of caffeine that is permitted and that it is the total amount of caffeine

Issue raised	Submitter(s)	FSANZ response
		from any source.
In subparagraph 2.9.4 — 3(1)(c)(ii) – recommends replacing the term 'caffeine' with 'caffeine from any source' for consistency in terminology.	NSWFA	FSANZ considers this is not required. Subsection 2.9.4—3(1)(c)(ii)(d) relates to the permission to add caffeine to a FSSF. It does not include the condition of how much caffeine is permitted. Therefore it is not necessary to specify here that it is total caffeine. Instead, paragraph 2.9.4—3(2)(c) specifies the amount of caffeine that is permitted and that it is the total amount of caffeine from any source.
Offers the following consequential amendments to existing provisions: • Subsection 1.1.2—3(2) (Definition of formulated beverage) – amend subparagraph (e)(ii) to 'does not contain caffeine from any source' for consistency in terminology. • Section 1.1.2—6 (Definition of formulated caffeinated beverage) – amend paragraph (a) to 'contains caffeine from any source' for consistency in terminology. • Subsection 1.2.4—7(6) – replace 'If caffeine is added' with 'If product that is caffeine that has been concentrated, refined, or synthesised is added', for consistent terminology. In Section S9—2 (advisory statements): • replace 'extracts of guarana' with 'guarana extract' for consistent terminology with section 1.1.1—10(7A) • replace 'cola beverage' with 'cola type drink' for consistent terminology • replace 'added caffeine' [a cola beverage that contains added caffeine] with 'product that is caffeine that has been concentrated, refined, or synthesised' for consistent terminology. Similar ambiguity applies to the formulated caffeinated beverage definition, which requires in paragraph (a) 'contains caffeine'. Whilst the compositional requirement for FCB in section 2.6.4—3 provides clarity that FCBs must contain 'no less than 145 mg/L and no more	NSWFA	FSANZ notes the suggested amendments to the definition of formulated beverage and Section S9–2 (advisory statements). These could be considered in a future Code Maintenance Proposal. Regarding the definition of FCB, FSANZ considers that the definition, when read in the context of the compositional requirement, is clear that caffeine means total caffeine from any source and has not amended this definition.

Issue raised	Submitter(s)	FSANZ response
than 320 mg/L of caffeine in total, from any source', by definition, it is unclear if the requirement in paragraph (a) refers to refined, and pure and highly concentrated caffeine products or caffeine from any source.		
Recommends replacing the term 'in a multi -pack' with a term explaining the nature of the particular type of FSSF. The meaning of the term 'multi -pack' is undefined and may be subject to dispute. Recommends an alternative phrase such as 'that consists of separate multiple individual portion packs'. The use of the term 'individual portion packs' will achieve consistency with sub section 1.2.1—6(3).	NSWFA	The term 'individual portion pack' is not used in subsection 2.9.4—12(5) because the definition of individual portion pack in the Code is not appropriate for the requirements set out in that section. The term 'individual portion' is used so that the labelling requirement in subsection 2.9.4—12(5) applies only to individual portions referred to in subsection 2.9.4—12(1). Subsection 2.9.4—12(1) sets out which FSSF the requirement applies to. The term 'multi-pack' is only used in the heading of section 2.9.4—12.
Supports the overall aim of Proposal P1056, which is to review caffeine permissions in foods, especially considering risks to sensitive sub-populations.	ABCL	FSANZ notes this support.
Significant caffeine exposure, particularly for vulnerable population groups, still remains a risk from products regulated by the Therapeutic Goods Administration (TGA) such as body building supplements. Urges collaboration between FSANZ and the TGA to ensure all caffeine-containing products are regulated, regardless of classification as food or therapeutic goods.	PHAA	FSANZ will continue to collaborate with the TGA. Further, FSANZ notes there is a mechanism for determining if a good is a food or a medicine under the Australia TGA Food Medicine Interface Guidance Tool.
Provides additional public health arguments supporting stronger regulation, including evidence. Recommends enhancing protections for children and adolescents, including sales restrictions and ongoing monitoring.	PHAA	Population groups considered in the assessment include the general population, pregnant and lactating women, adolescents, children, athletes and other potentially sensitive sub-populations (SDs 1, 2 and 3). FSANZ found little substantiated evidence that adolescents or children are regularly consuming caffeine in excess of their respective safe recommended limits (see SD1 of the 1st CFS). Tea

Issue raised	Submitter(s)	FSANZ response
		and coffee and coffee substitutes and soft drinks contributed to the majority of caffeine intake in adolescents (see SD 2 of the 1st CFS).
The 200 mg quantity is based on a labelled quantity. There is no information on the permitted amount of variability for manufacturing purposes. For example, in a therapeutic good, the permitted variation for a substance such as caffeine is commonly 90-120% for manufacturing tolerance.	CMA	Manufacturing tolerances are not set out in the Code. The Code will prescribe a 200 mg one-day quantity of caffeine in FSSF.
Suggests reconsidering the premise that individually packaging small portions of FSSF will reduce risk of overconsumption, particularly for vulnerable subpopulations.	NZFS	This issue was raised by submitters in response to the 2nd CFS and considered by FSANZ. FSANZ's response to the submission is in Table 2, Appendix 1 of the Approval Report under the heading 'Packaging of solid or semi-solid caffeine-containing FSSF in a multi-pack'. In summary, individual packaging is considered just one aspect of a broader risk management strategy. FSANZ considers the risk management approach appropriate for managing the risk.

Appendix 3: FSANZ response to issues raised in submissions to the WTO SPS notification

Table 1 – *Summary of submitter comments to the New Zealand WTO SPS Notification and FSANZ response*

Issue raised	Submitter/s	FSANZ response
Considers the proposed labelling requirements for high caffeine coffee beverages do not address labelling requirements for other beverages naturally high in caffeine such as tea beverages. For transparency, submitter requests FSANZ clarify whether products that contain caffeine from other natural sources are also required to label, to avoid unnecessary trade barriers.	China	The labelling requirements in section 2.10.4—3A only apply to beverages containing coffee. These labelling requirements were prepared in response to concerns from submitters specifically about beverages containing coffee that are high in caffeine. FSANZ is not aware of beverages with the same high levels of caffeine (over 200 mg per serving) from tea.