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

31 October 2025
365-25

Consultation paper – naturally occurring caffeine and labelling

P1056 – Caffeine review

The purpose of this consultation paper is to seek views on additional proposed changes in relation to permissions for caffeine in sports foods and in the general food supply.

In March 2025, pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), Food Standards Australia New Zealand (FSANZ) sought submissions on its assessment and draft variation to the Code. After consideration of submissions, FSANZ has revised the draft variation and now seeks submissions on those revisions. Submissions received in response will inform FSANZ's decision on whether to approve, amend or reject revised draft variation. If approved by FSANZ, the revised draft variation will be referred to the Food Ministers' Meeting for consideration and endorsement.

Submissions on this proposal need to be made through the Consultation Hub.

All submissions on applications and proposals will be published on the Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published following consultation and before the next stage in the statutory assessment process.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at Making a submission.

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

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

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 12 December 2025

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

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

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

Submissions in hard copy may be sent to the following addresses:

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Executive summary

Proposal P1056 – *Caffeine review* was raised by Food Standards Australia New Zealand (FSANZ) to assess whether amendments to the Australia New Zealand Food Standards Code (the Code) are required to provide additional regulatory measures for caffeine in the Australian and New Zealand food supply in order to protect public health and safety.

The proposal's scope includes:

- the addition of caffeine to Formulated Supplementary Sports Foods (FSSF), and other foods in the general food supply, and
- the extent of the risk posed to 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.

The proposal is being assessed under FSANZ's major procedure, which requires two rounds of statutory public consultation. The first round of public consultation on FSANZ's assessment and preliminary conclusions occurred in December 2022 (1st Call for Submissions (CFS)). After considering all submissions received, FSANZ prepared a draft variation to the Code that, if approved, would:

- prohibit the retail sale of caffeine as a food unless expressly permitted by the Code
- prohibit a food for retail sale from containing caffeine as an ingredient or component unless expressly permitted by the Code
- in light of the above, remove the current Code prohibition on a food for retail sale containing caffeine in a concentration of 5% or more for solid or semi-solid food and 1% or more for liquid food
- expressly permit FSSF to contain caffeine up to 200 mg in a one-day quantity (the amount of FSSF which is to be consumed in one day in accordance with directions specified on the label)
- set new compositional, packaging and labelling requirements for FSSF, including a requirement that a FSSF must not contain caffeine at a concentration of:
  - 5% or more for a FSSF in a powdered form; or
  - 1% or more for a FSSF in a liquid form.

Submissions were sought on the draft variation in March 2025.

After considering the submissions received, and for the reasons set out in this consultation paper, FSANZ is proposing to amend the draft variation. The proposed additional amendments include:

- a new prohibition on the retail sale of guarana extract as a food unless expressly permitted by the Code
- amending the proposed prohibition on a food for retail sale from containing caffeine as an ingredient or component to make clear the prohibition applies and relates to caffeine 'from all sources', including from the addition of pure caffeine or guarana extract
- amending subsection 1.1.1—10(7) to provide examples of what is caffeine in a food for sale or an ingredient of a food for sale 'by natural occurrence'
- new subsection 1.1.1—10(7A), which states subsection 1.1.1—10(7) does not apply to guarana extract, and which makes clear caffeine from guarana extract is subject to the above prohibition on food for retail sale from containing caffeine as an ingredient or component

- requirements for packaged coffee-containing beverages with 200 mg or more of caffeine per serve to display an advisory statement and to declare the caffeine content per serve and per unit quantity in the nutrition information panel
- amending the caffeine-related labelling requirements for FSSF proposed at the 2nd CFS so that these do not apply to FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and decaffeinated coffee
- new labelling requirements for certain FSSF containing more than 200 mg caffeine in total and sold in a multipack.

FSANZ seeks views on each of the above proposed additional amendments and, for this purpose, has prepared a revised draft variation that includes each amendment. Submissions are sought only on the above proposed amendments. The other aspects of the draft variation were consulted on at the 2nd CFS and are out of scope for this targeted consultation exercise.

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

1 Introduction

1.1 The Proposal

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

The scope of the proposal includes:

- the addition of caffeine to Formulated Supplementary Sports Foods (FSSF) and other foods in the general food supply, and
- the extent of the risk posed to 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)(FSANZ, 2019b). 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 2019b), the FSANZ Board approved a variation to the Australia New Zealand Food Standards Code (the Code) to prohibit the retail sale of pure and highly concentrated caffeine products.

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

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

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

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

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

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

For the reasons stated in the P1054 ‘Amendment of the approved variation’ report (FSANZ 2020), FSANZ decided to prepare a further proposal under the FSANZ Act. The P1054 report stated that the proposal would *consider whether additional measures are required in*

relation to caffeine in the Australian and New Zealand food supply in order to protect public health and safety; in particular:

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

P1056 is that proposal. The approved variation prepared under P1054 will remain unchanged and in force until the completion of P1056. This ensures ongoing protection of consumers from pure and highly concentrated caffeinated 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. The Major Procedure requires two statutory rounds of public consultation which have now been completed.

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

After considering the submissions received in response to the 1st CFS, FSANZ decided to prepare a proposed draft variation (FSANZ, 2022, Attachment A). The 2nd CFS (FSANZ 2025), released on 4 March 2025, sought feedback on the draft variation and the assessment and regulatory approach on which it was based.

Submissions received in response to the 2nd CFS have informed FSANZ's decision to revise several of the proposed amendments set out below in section 2.

1.4 The current standards

1.4.1 The Code

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.

1.4.1.1 Addition of caffeine to food

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

1.4.1.2 Processing aids

Paragraph 1.1.1—10(6)(c) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance *used as a processing aid* unless that substance's use as a processing aid is expressly permitted by the Code. There is no permission for the use of caffeine as a processing aid in the Code.

1.4.1.3 Food additives

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

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

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

Schedule 16 sets out the types of substances that may be used as food additives in any processed food at Good Manufacturing Practice (GMP)[1] levels. The entry for 'Permitted flavouring substances' in tables to section S16—2 specifically excludes caffeine. Therefore, any food categories in the table to section S15—5 allowing 'additives at GMP' or 'Permitted flavouring substances' are not permitted to contain caffeine within any flavouring preparation added to these food categories.

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[1] 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.

1.4.1.4 Nutritive substances

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

1.4.1.5 Novel foods

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

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

Subsections 1.1.1—10(8) and (9) provide that, if a labelling or an information requirement of the Code applies to the sale of a food, labelling for that food must comply with the requirement, or the information must be provided as required, respectively.

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'[2]—no more than a one-day quantity should be consumed per day. Caffeine is not a 'listed substance'.

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

1.4.1.8 Prohibition of pure and highly concentrated caffeine products

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

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

1.4.2 Therapeutic Goods Administration

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

On 30 November 2020, the TGA created a legislative instrument under section 7 of the *Therapeutic Goods Act 1989* (TG Act) to help protect Australian consumers from the unsafe use of certain sports supplements. Under the TG Act, some sports supplements containing caffeine are declared to be a therapeutic good. This depends on a number of factors, including the daily dose of caffeine. As a result, caffeine containing sports foods, which meet the requirements of section 7 of the TG Act are now 'therapeutic goods' for the purposes of the TG Act. This means that these products are not regulated as 'a food', and the FSANZ Act, Australian and New Zealand food laws and the Code do not apply to them. For further background, refer to section 2.2 of the Amendment Report for P1054 – Pure and highly concentrated caffeine products (FSANZ 2020) and information on the TGA website.[3]

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

The Poisons Standard

The Poisons Standard exempts nearly all food from being a poison. Advice to FSANZ is exemptions in the Poisons Standard mean any restrictions imposed as a result of listing as a poison can only apply to the following foods:

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[2] 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.

[3] 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[4] (also cited as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)).

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

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

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

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

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

1.4.3 The New Zealand Food (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.[7] 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*[8] 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

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[4] Federal Register of Legislation - Therapeutic Goods (Poisons Standard—June 2024) Instrument 2024
[5] 2.1 Caffeine | Therapeutic Goods Administration (TGA)
[6] Understanding storage requirements for Schedule 6 and Schedule 7 chemicals in retail settings | Therapeutic Goods Administration (TGA)
[7] Importing food from New Zealand - DAFF (agriculture.gov.au)
[8] *New Zealand Supplemented Food Standard 2016*

ordinarily apply in New Zealand continue to apply to the supplemented food without modification. This includes paragraph 1.1.1—10(5)(g) of the Code, which currently sets maximum limits for the concentration of caffeine in food.

1.4.4 Regulation of caffeine internationally

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

2 Proposed revisions to the draft variation.

This section discusses additional changes to the proposed drafting for caffeine in response to issues raised as part of the second CFS. These changes are to:

- Prohibit the retail sale of guarana extract as a food unless expressly permitted by the Code.
- Clarify the proposed prohibition on a food for retail sale from containing caffeine as an ingredient or component to make clear the prohibition applies and relates to caffeine 'from all sources', including from the addition of pure caffeine or guarana extract.
- Amend subsection 1.1.1—10(7) to provide examples of what is caffeine in a food for sale or an ingredient of a food for sale 'by natural occurrence'.
- Insert a new subsection 1.1.1—10(7A), which states subsection 1.1.1—10(7) does not apply to guarana extract, and which makes clear caffeine from guarana extract is subject to the above prohibition on food for retail sale from containing caffeine as an ingredient or component.
- Require packaged coffee-containing beverages with 200 mg or more of caffeine per serve to display an advisory statement and to declare the caffeine content per serve and per 100 mL in the nutrition information panel.
- Amend the caffeine-related labelling requirements for FSSF proposed at the 2nd CFS so that these do not apply to FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and decaffeinated coffee.
- Set new labelling requirements for certain FSSF containing more than 200 mg caffeine in total and sold in a multipack.

Each of these proposed additional amendments is discussed below.

A revised draft variation including these amendments is at Attachment A, with a related Explanatory Statement at Attachment B. A copy of the draft variation as proposed at the 2nd CFS is at Attachment C for comparison.

To reiterate, this paper's purpose is to consult only on the above proposed new changes. All other unchanged aspects of the draft variation were consulted on at the 2nd CFS and are out of scope for this consultation. Note the proposed amendments do not constitute a complete or definitive list of the drafting changes that may be made to the draft variation.

2.1 Submitters responded to in this consultation paper

This consultation paper does not include all issues raised by submitters in response to the 2nd CFS. FSANZ's responses to all 2nd CFS submitters will be provided in its decision report following this consultation.

Table 1 lists the submitters who raised concerns during the 2nd CFS and whose issues are addressed in this consultation paper.

Table 1: Submitters to the 2nd CFS where responses are provided in this paper

Organisation	Abbreviation
Australian Beverages Council	ABCL
Australian Food and Grocery Council	AFGC
Complementary Medicines Australia	CMA
Edith Cowan University	ECU
Healthcare Product Specialists	HPS
New South Wales Poisons Information Centre	NSWPIC
New South Wales Food Authority	NSWFA
New Zealand Food and Grocery Council	NZFGC
New Zealand Food Safety	NZFS
Pharmacare Laboratories	PL
Queensland Health	QLDH
Western Australia Department of Health	DoHWA

2.2 Issues raised at the 2nd CFS regarding guarana extract, naturally occurring caffeine and high caffeine coffee beverages

2.2.1 The prohibition of caffeine as a food for retail sale, and as an ingredient, and plant extracts including guarana

The draft variation at the 2nd CFS

The draft variation at the 2nd CFS proposed an amendment to the Code to provide that, unless expressly permitted by the Code:

- caffeine must not be a food for retail sale; and
- a food for retail sale must not contain caffeine as an ingredient or component.

The reasons or rationale for this amendment are explained in the 1st and 2nd CFS.

FSANZ's assessment was that the above meant that the restrictions currently imposed by paragraph 1.1.1—10(5)(g) of the Code would no longer be required. Paragraph 1.1.1—10(5)(g) provides that, unless expressly permitted by the Code, a food for retail sale cannot be a food in which caffeine is present at a concentration of 5% or greater for a solid or semi-solid food; or 1% or greater for a liquid food.

FSANZ considered these restrictions were no longer required as:

- the proposed prohibition on the retail sale of caffeine would capture pure caffeine,

- the proposed prohibition on the retail sale of foods containing caffeine as an ingredient or component would capture highly concentrated products (such as milk powder mixed with caffeine or guarana extract),
- the two categories of products considered to pose a risk under P1054 would therefore be captured and regulated by the Code, noting that some of these products are regulated as therapeutic goods (see section 1.4.2 above),
- existing Code permissions to add caffeine to cola-type drinks and FCBs and the proposed new permission for FSSFs (FSANZ 2025, section 2.2.3), would provide consumers with continued safe and reasonable access to products with added caffeine despite the above prohibitions, and
- food businesses wanting to add caffeine to foods where there is no specific permission, or to amend existing permissions, could apply to FSANZ to amend the Code.

For these reasons, the draft variation also proposed to amend the Code to remove the above restrictions currently imposed by paragraph 1.1.1—10(5)(g).

The draft variation did not seek to define and expressly regulate caffeine-rich extracts as 'caffeine' or to apply a total caffeine limit to all foods. As explained in the 2nd CFS, FSANZ's assessment was 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.

  Note 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. Nor would it permit the retail sale of a food that has a caffeine-containing plant that is an unapproved novel food as an ingredient. Subsection 1.1.1—10(7) provides an exemption to the prohibitions imposed by subsection 1.1.1—10(6). It provides that subsection 1.1.1—10(6) does not apply to a substance (e.g., caffeine) that is present in a food for sale, or in an ingredient of a food for sale, by natural occurrence.

- The compositional limits that apply to foods currently permitted by the Code to contain added caffeine such as FCBs and cola-type drinks as well as the limits proposed in the draft variation for FSSF.

Submissions received

Some submissions received in response to the 2nd CFS (see Table 2) raised several issues in relation to the above approach, particularly regulation of highly concentrated caffeinated products and the removal of the restrictions imposed by paragraph 1.1.1—10(5)(g) which apply to any food for retail sale.

Table 2 Summary of issues – prohibition of caffeine as a food for retail sale and as an ingredient or component in for retail sale

Issue	Raised by	FSANZ response
The variation should also regulate the retail sale of caffeine (of various concentrations), extracts and concentrates very high in 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. It is necessary to ensure that variations to the Code explicitly state caffeine (as a substance or a concentrated extract) must not be added to food (or sold as a food) unless specifically 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.	QLDH	After consideration of submissions, and for the reasons summarised in section 2.2.1.1 and 2.2.1.2 below, FSANZ proposes amending the draft variation to: • include a new prohibition on the retail sale of guarana extract as a food unless expressly permitted by the Code; • clarify 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', including from the addition of pure caffeine or guarana extract; • provide examples in the Code for the purposes of 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'.

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. 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.	NZFS	See above response. After consideration of submissions, and for the reasons summarised in section 2.2.1.2 and 2.2.2 below, FSANZ has proposed amendments to the draft variation in relation to guarana extract. For caffeine-containing plant extracts, FSANZ maintains its view at the 2nd CFS that some 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. As above, FSANZ has clarified 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', including from the addition of pure caffeine or guarana extract. The issue relating to natural occurrence is addressed in Table 3 and section 2.2.2 below.

Issue	Raised by	FSANZ response
Regarding the proposals to limit caffeine in powders and liquids to 5% and 1%, respectively, the current draft Code refers only to 'caffeine'. While the intent of this is to capture highly concentrated and pure caffeine, it remains open to interpretation. Without this clarity, and with the removal of the current Code prohibition on a food for retail sale containing caffeine in a concentration of 5% or more for solid or semi-solid food; or 1% or more for liquids, high-caffeine plant extracts in foods could be used, potentially bypassing the 200 mg daily limit for formulated caffeinated products.	CMA	See above responses. FSANZ maintains that the 1 and 5% concentration limits in general foods are not required given the amendments to the Code that would be made by the revised draft variation and the unchanged parts of the draft variation provided at the 2nd CFS, together with the other existing provisions of the Code referred to above.
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	See above responses.
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. 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.	NZFS	See responses above. The draft variation, amended as proposed above, will prohibit guarana extract as a food for retail sale and, as added guarana extract is a source of caffeine, as an ingredient or component in a food for retail sale unless expressly permitted by the Code (currently only in FCBs and FSSF). The latter in effect extends to the presence of caffeine in smoothie bases and alcoholic beverages due to the addition of guarana extract. FSANZ considers these measures will appropriately manages the risk of overconsumption of caffeine associated with the use of guarana extracts. These measures also mean that the concentration limits for general foods are no longer required. Regarding guarana extract, the proposed prohibition on a food for retail sale containing caffeine as an ingredient or component applies and relates to caffeine 'from all sources', including from the addition of guarana extract.

Issue	Raised by	FSANZ response
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.	PL	FSANZ does not consider a definition of caffeine specifying permitted sources of caffeine is warranted. FSANZ has proposed an amendment to the draft variation to clarify 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', including from the addition of pure caffeine or guarana extract. See responses above. After consideration of submissions to the 1st and 2nd CFS, and for the reasons summarised in section 2.2.1.2 below, FSANZ has also proposed an amendment to 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 as a permitted novel food; and any conditions of use prescribed by the Code for novel that food are complied with.
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 responses above. FSANZ is proposing to amend the draft variation to: • clarify 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', including from the addition of pure caffeine or guarana extract; • provide examples in the Code for the purposes of 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' (see section 2.2.2). • clarify, through a new provision, 1.1.1—10(7A) that guarana extract is not captured by the natural occurrence provision in 1.1.1—10(7) (see section 2.2.2)

2.2.1.1 Discussion

Guarana extract – when sold as a food for retail sale and for use as an ingredient

The draft variation at the 2nd CFS did not expressly regulate guarana extract as a food for retail sale. It, instead, only sought to prohibit the sale of caffeine as a food for retail sale. FSANZ's intent was that the prohibition on the addition of caffeine to food constituted a prohibition on all sources of caffeine, regardless of the origin. The prohibition aimed to prevent the addition of highly concentrated sources of caffeine to food as per the intent of proposal P1054. FSANZ's intent in this regard has not changed.

FSANZ notes:

- guarana extract can be a highly concentrated source of caffeine (guarana extract is produced to a range of different caffeine contents such as standardised to 22% caffeine; but can be much higher)
- the use to date in the Australia and New Zealand food supply of guarana extract as an ingredient, including in concentrated forms, is because of its caffeine content and FSANZ is aware of guarana extract powders (containing around 22% caffeine) that can be bought online as a food for sale
- the risks identified by submitters and corroborated by FSANZ in relation to the use of guarana extracts in food by virtue of its caffeine content
- a lack of regulatory certainty regarding guarana extract due to its concentrated nature and resultant caffeine content

In view of the above and for the reasons summarised in this paper, FSANZ proposes to revise the draft variation to include an amendment to the Code to provide that guarana extract cannot be sold as a food for retail sale.

Further, FSANZ proposes to amend the draft variation to clarify that the proposed prohibition on a food for retail sale containing caffeine as an ingredient or component (unless expressly permitted elsewhere in the Code) applies and relates to caffeine 'from all sources', including from the addition of guarana extract. Note that for manufacturers of FCBs and FSSF that use guarana extract as a source of caffeine, the new proposed amendments do not change their ability to do so, subject to the respective Code requirements.

Each of these amendments align with the objectives of proposal P1054 and the outcomes of the P1056 Risk Assessment (FSANZ 2025, SD1) by reducing the likelihood of overconsumption of caffeine, via highly caffeinated products, the protection of sensitive sub-populations and the prevention of these products becoming more widespread in the general food supply.

Other plant extracts high in caffeine

FSANZ's position on other plant extracts high in caffeine remains unchanged, noting the following.

- Use of these extracts will be subject to the prohibition on food for retail sale containing caffeine as an ingredient or component unless expressly permitted.
- The compositional and other requirements imposed by the Code, as amended by the revised draft variation, in relation to food for sale containing caffeine.
- 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 sold as a food at retail sale or be present in a food for retail sale as an ingredient or component.

To provide further clarification on caffeine containing plant extracts, FSANZ proposes to include in the draft variation an amendment to Standard 1.5.1 of the Code to clarify 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 novel that food are complied with. This is to make it clear that in circumstances where caffeine is permitted 'from any source' as an ingredient or component (e.g. in FCBs or FSSF), the words 'from any source' does not automatically extend a permission to caffeine that is, part of or derived from a novel food.

See also discussion on caffeine by natural occurrence below relating to subsection 1.1.1—10(7).

2.2.1.2 The proposed amendments

FSANZ is proposing to make the following changes to the draft variation.

New prohibition - prescribed caffeine products

The draft variation will 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.

See Item [1] of the Schedule to the revised draft variation at Attachment 1.

Clarification – caffeine from any source prohibited in food for retail sale

The draft variation will 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.

See Item [2] of the Schedule to the revised draft variation at Attachment 1.

Clarification – caffeine from novel food prohibited unless novel food permitted

The draft variation will amend section 1.5.1—3 by adding subsection 1.5.1—3(3). The new subsection will provide that, despite any other provision of the Code, 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 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.

This 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 caffeine that is, part of or naturally contained within a novel food. Premarket assessment and approval as a novel food will be required.

See Item [9] of the Schedule to the revised draft variation at Attachment 1.

2.2.2 Caffeine in a food by natural occurrence

The draft variation at the 2nd CFS

The draft variation sought to amend subsection 1.1.1—10(6) of the Code to prohibit caffeine's presence as an ingredient or component in a food for retail sale unless that presence was expressly permitted by the Code.

This prohibition would be subject to subsection 1.1.1—10(7) of the Code. That subsection provides an exemption to the prohibitions imposed by section 1.1.1—10(6). Subsection 1.1.1—10(7) states that 'Subsection (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.'

As a result, the proposed new prohibition on food for retail sale containing caffeine as an ingredient or component would not to apply to or prohibit caffeine that is in a food for retail sale, or in an ingredient of a food for retail sale, by natural occurrence. Food businesses could continue to sell foods such as coffee, tea and chocolate that contain caffeine by natural occurrence and to add ingredients that contain caffeine by natural occurrence to a food for sale (such as adding coffee or chocolate to a cake or confectionery).

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.

Submissions received

Submissions received in response to the 2nd CFS raised several issues in relation to the above approach. These issues are summarised below in Table 3.

Table 3 Summary of issues – caffeine by natural occurrence

Issue	Raised by	FSANZ response
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 NZFS	FSANZ is proposing several revisions to the draft variation to clarify when caffeine from plant sources is prohibited. See above in section 2.2.1.2. Further, FSANZ's position on coffee, tea, cocoa and other plant extracts permitted in the Code as sources of caffeine remains unchanged. FSANZ is proposing to amend the Code to include examples in the Code for the purposes of 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' (section 2.2.2.2 below).
Herbal extracts, flavours or propriety 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	The proposed prohibition on a food for retail sale containing caffeine as an ingredient or component would not to 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. See subsection 1.1.1—10(7) of the Code. 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.

Issue	Raised by	FSANZ response
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 proposed at the 2nd CFS and in this consultation paper address the submitter's concern regarding the removal of the P1054 limits. These amendments include: • the prohibition via subsection 1.1.1—10(5) on the retail sale of caffeine and of guarana extract as a food; • 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' (section 2.2.1); • the examples in the Code for the purposes of 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' (section 2.2.2.2 below); • the proposed 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 (section 2.2.2.2 below); and • new labelling requirements for coffee-containing beverages with high levels of caffeine sold for retail sale (see section 2.2.3). FSANZ also notes the evidence-based risk assessment. This found that most of the Australian and New Zealand population were consuming caffeine within the safe limits.

2.2.2.1 Discussion

After consideration of submissions, and for the reasons set out in the sections above, FSANZ's position on caffeine by natural occurrence and on subsection 1.1.1—10(7) remains unchanged.

However, given stakeholder uncertainty about the operation of subsection 1.1.1—10(7), FSANZ is proposing to include examples in the Code for the purposes of what is caffeine in a food for sale or an ingredient of a food for sale 'by natural occurrence' and an additional provision in 1.1.1—10(7A) to clarify that guarana extract is not considered to contain caffeine by natural occurrence (due to its high caffeine content, refer to section 2.2.1.1 above).

Subsection 1.1.1—10(7) is an exemption only for subsection 1.1.1—10(6). Subsection 1.1.1—10(7) does not apply to any other provision of the Code. Subsection 1.1.1—10(6) prohibits the presence of a prescribed substance (in this case caffeine) in a relevant food for sale as an ingredient or component unless that presence is expressly permitted in and by the Code. Subsection 1.1.1—10(7) would provide this prohibition does not apply to or prohibit caffeine that is in a relevant food for sale, or in an ingredient of such a food, by natural occurrence.

Subsection 1.1.1—10(7) does not apply to or deal with compositional requirements imposed by other provisions of the Code such as subsection 1.1.1—10(3) of the Code.

The Code sets or will set maximum limits for caffeine present in certain kinds of food for sale (e.g., in FCBs or FSSF). Code provisions other than subsection 1.1.1—10(6) require those foods for sale to comply with those compositional limits. As mentioned above, guarana extract will continue to be a permitted source of caffeine in instances where there is a permission in the Code for the addition of caffeine (i.e., in FCBs and FSSF), subject to the relevant compositional limits and labelling requirements. In these cases, these limits are or will be stated to apply to caffeine 'from any source'. That is, to caffeine from all dietary sources, which includes, for example, naturally occurring caffeine and guarana extract.

2.2.2.2 The proposed drafting changes

FSANZ is proposing to make the following changes to the draft variation.

The draft variation will amend 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 will 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.

Proposed subsection 1.1.1—10(7A) removes any potential argument as to whether subsection 1.1.1—10(7) applies to and exempts guarana extract that is in a food for retail sale (as an ingredient or component) or that is in an ingredient of a food for retail sale.

2.2.3 Naturally occurring caffeine – coffee-containing beverages high in caffeine

As stated above, FSANZ has not previously proposed any amendments to the Code for general food products with added ingredients or components containing caffeine by natural occurrence

Throughout P1056, FSANZ's intent has been that the proposed amendments would not impact the sale of foods such as coffee, teas and chocolate that contain caffeine by natural occurrence. The compositional requirements for these foods are included in the Code in Standard 2.10.4 – *Miscellaneous standards for other foods*. In addition, due to the exemption provided by subsection 1.1.1—10(7), the proposed prohibition imposed by paragraph 1.1.1—10(6)(k) will not apply to caffeine that is in a food for sale, or in an ingredient of a food for sale, by natural occurrence.

Submissions received in response to the 2nd CFS raised issues in relation to the above approach, particularly regulation of coffee containing beverages high in caffeine. These issues are summarised below in Table 4.

Table 4 Summary of issues – coffee containing beverages high in caffeine

Issue	Raised by	FSANZ response
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 concerned 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 acknowledges there are beverages containing coffee that have high levels of caffeine and, for the reasons set out below, is proposing additional labelling measures in line with the FSANZ risk assessment and to provide more consumer information in these instances (see section 2.2.3.1 below). 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 below.

Issue	Raised by	FSANZ response
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. This submitter proposes 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). • 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.	NSWFA	FSANZ's risk assessment identified that most people are consuming under the safe 400 mg/day level without labelling requirements for caffeine in general foods. FSANZ notes concerns from submitters about certain beverages containing high caffeine levels from coffee and recognises that information provision would support consumers to manage their caffeine intake from these products. We are therefore proposing new labelling requirements for coffee-containing beverages with 200 mg or more caffeine per serving (see section 2.2.3.1 below). 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 below.
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	See response above.

Issue	Raised by	FSANZ response
The lack of measures to limit the caffeine concentration of food for retail sale where caffeine is naturally occurring. The removal of the general limits for caffeine concentration in food for retail sale that were introduced as part of P1054 may see an inadvertent increase in highly caffeinated products from natural sources e.g. ready-to-drink highly concentrated coffee beverages.	DoHWA	See responses above in relation to subsection 1.1.1—10(7) and the removal of the current limits for caffeine concentration in food for retail sale set by paragraph 1.1.1—10(5)(g). See also response above in relation to compositional limits in foods that contain naturally occurring caffeine and the new labelling requirements for coffee-containing beverages with 200 mg or more caffeine per serving (see section 2.2.3.1 and 2.3.2 below).

2.2.3.1 Discussion

As noted by submitters, packaged beverages containing coffee with a caffeine content of greater than 200 mg per serve are available in the domestic market. Many of these products are ready-to-drink beverages (e.g., iced coffees), while other products are coffee concentrates that require reconstitution. Submitters raised that there is no compositional limit for general foods that contain naturally occurring caffeine, and no requirement to provide consumers, including consumers sensitive to caffeine, information about the amount of caffeine these products contain.

FSANZ's risk assessment (FSANZ 2025, SD1, 2 and 3) found that adverse effects are observed from acute intake of caffeine at amounts greater than 200 mg in healthy, non-pregnant adults. However, FSANZ notes this level is substantially lower than the amount of caffeine that is likely to induce caffeine toxicosis (FSANZ 2022, SD1). The risk assessment also found that the total safe amount of caffeine per day for healthy, non-pregnant adults is 400 mg. The risk assessment found that caffeine consumption is typically self-limiting and most people in Australia and New Zealand consume under the total safe daily limit. However, the small percentage (6%) of consumers that exceeded this amount did so mostly through tea and coffee consumption.

The risk assessment also concluded the safe recommended limit for pregnant women is 200 mg per day and children are at risk of caffeine toxicosis due to their low bodyweights. FSANZ's social science assessment found that up to 15% of pregnant women may be exceeding the safe 200 mg/day caffeine dose.

Based on this risk assessment, a coffee-containing beverage with more than 200 mg of caffeine per serve would contribute at least 50% of the recommended maximum daily limit for healthy, non-pregnant adults. For pregnant women, it would constitute 100% of their recommended maximum daily limit. FSANZ recognises that there is currently no requirement for these beverages to inform consumers of the relatively high amount of caffeine they contain. However, FSANZ's risk assessment also found that most consumers manage their caffeine consumption within the total safe daily amount of caffeine, and FSANZ considers the risk of severe adverse effects from beverages containing caffeine only from coffee, including beverages which exceed 200 mg per serving, is low for non-pregnant adults.

Regarding stakeholder suggestions of a compositional limit on caffeine in coffee-containing beverages, FSANZ considers this degree of regulatory intervention is not proportionate with the level of risk posed by these products. It would also be challenging to enforce unless associated with labelling of the amount of caffeine present on all coffee beverages, regardless of the amount of caffeine they contain. However, FSANZ considers it would be appropriate for consumers to be informed of the caffeine content of these higher caffeine coffee products to assist them in managing their caffeine intake.

Therefore, after considering the risk assessment, current industry practice and stakeholder comments, FSANZ considers 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.

FSANZ is proposing two advisory statements and to require caffeine to be declared 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 a NIP in accordance with section 1.2.8—5 of the Code.

Under this approach, the proposed labelling would not be required for coffee beverages that are exempt from the requirement to bear a label (subsection 1.2.1—6), for example, if they are made and packaged from the premises from which they are sold, or packaged in the presence of the purchaser, such as, a cup of coffee purchased from a café.

The proposed labelling would also not be required for coffee beans (including ground) and instant coffee. These are 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). See section 2.5.1 for discussion on costs and benefits relating to these requirements.

Advisory statements

The proposed advisory statements are statements 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. This is similar to the advisory statements required for formulated caffeinated beverages in subsection 2.6.4—5(3) of the Code.

Words to the effect of 'high in caffeine' are proposed because a beverage that has 200 mg or more of caffeine per serve would contain 50% or greater of the recommended maximum daily limit for healthy, non-pregnant adults (400 mg). It also provides context for the other proposed advisory statement about suitability.

Words to the effect that the beverage is not suitable for children under 15 years of age or pregnant or breastfeeding women reflects the risk assessment findings that the recommended maximum daily limit for pregnant women is 200 mg of caffeine, that a portion of caffeine circulating in the bloodstream enters breastmilk, and that infants and small children are at higher risk of acute caffeine toxicity due to their low bodyweights (FSANZ 2025, SD1). The intent of the new requirement is to inform consumers who are pregnant or breastfeeding women, children or caregivers of children that the food is not recommended for them.

FSANZ is not proposing to require the advisory statement to refer to 'individuals sensitive to caffeine'. The reasons described in section 2.2.9.2 of the 2nd CFS (FSANZ 2025) for the FSSF warning statement would also apply to beverages containing coffee, i.e., the proposed labelling information about the presence and amount of caffeine and likely knowledge of this population group about caffeine consumption would be sufficient to manage risks.

Declaration of caffeine in the NIP

Under the proposed approach, packaged beverages containing coffee with caffeine in amounts of 200 mg or more per serving would be required to declare the average quantity of caffeine in the NIP on a per serving and per unit basis. Nutrition information requirements in Standard 1.2.8 apply to these products. The declaration for caffeine would be required under sodium in the NIP.

As noted for FSSF in section 2.2.9 of the 2nd CFS, the proposed requirement to declare the average quantity of caffeine in the NIP of a packaged beverage containing coffee would mean that such a declaration is not a nutrition content claim (subsection 1.1.2—9(2) of the Code).

The declaration requirement would inform consumers of the amount of caffeine present in a serving and per unit quantity. Consumer evidence indicates that consumers tend to self-regulate consumption of coffee and tea, however, are unlikely to know these packaged beverages contain high amounts of caffeine (unless manufacturers provide this information voluntarily) (FSANZ 2025, SD3).

2.2.3.2 The proposed drafting changes

New labelling requirements for high caffeine coffee beverages

The draft variation will amend Standard 2.10.4 by adding section 2.10.4—3A to that Standard. The new section will 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.

See Item [16] of the Schedule to the revised draft variation at Attachment 1.

For the purposes of the above, the draft variation will amend Standard 1.1.2 to include a definition of a *high caffeine coffee beverage* in section 1.1.2—3. The definition will 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 will state that formulated caffeinated beverages and formulated supplementary sports foods are not *high caffeine coffee beverages*.

See Item [6] of the Schedule to the revised draft variation at Attachment 1.

2.3 Labelling of FSSF

2.3.1 Labelling when caffeine is present from certain ingredients in FSSF

The draft variation at the 2nd CFS

The draft variation sought to amend the Code to require the following new labelling requirements for FSSF containing caffeine:

- an advisory statement using wording to the effect of 'contains caffeine' (Schedule 9)
- declaration in the NIP of the average quantity of caffeine present (section 2.9.4—11)
- a new warning statement for FSSF containing caffeine that specifies it is not suitable for children under 15 years of age, or pregnant or breastfeeding women (section 2.9.4—4(1)(a)(iv)).

The labelling requirements in the draft variation would apply irrespective of the source or amount of caffeine present in the FSSF.

Submissions received

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.

These issues are summarised below in Table 5 below.

Table 5 Summary of issues – Labelling of caffeine present from certain ingredients in FSSF

Issue	Raised by	FSANZ response
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. 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.	HPS	After consideration of submissions, and for the reasons summarised in section 2.3.1.1 below, FSANZ is proposing to amend the draft variation to exempt FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee (including instant versions of these) from the proposed labelling requirements, including the warning statement requirement. FSANZ considers that this approach means a quantifiable caffeine threshold is not necessary.
The submitter asked for clarification regarding the declaration of residual levels of caffeine and the warning statement in a FSSF that only contains caffeine via natural occurrence, and no added synthetic caffeine e.g. a mocha-chocolate flavoured FSSF powder. 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. Clear guidance and clarification is requested, with HPS recommending a quantifiable level of caffeine (either as an added ingredient or naturally occurring) before the labelling requirements are needed.	HPS	See above response.

Issue	Raised by	FSANZ response
The submitter 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	After consideration of submissions, and for the reasons summarised in section 2.3.1.1 below, FSANZ is proposing to amend the draft variation to exempt FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee (including instant versions of these) from the proposed labelling requirements, including the requirement to declare in the NIP the average quantity of caffeine present in the FSSF.
Submitter 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	See above response.
The submitter 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	For the reasons summarised in section 2.3.1.1 below, FSANZ is proposing to exempt FSSF containing caffeine only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee from the proposed labelling requirements. FSANZ considers this approach to be the minimum effective regulation for the presence of caffeine in FSSF whilst recognising the significant cost burden of relabelling for manufacturers using cocoa, chocolate or decaffeinated tea or coffee for flavouring in FSSF.

2.3.1.1 Discussion

FSANZ considers the regulatory impact imposed when caffeine is present in a FSSF only as a result of its natural occurrence in certain ingredients (cocoa, chocolate, and decaffeinated tea or coffee) is not justified due to the minimal amounts of caffeine they contain.

FSANZ is proposing to exempt 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 sources (in addition to or instead of these ingredients), the caffeine-related labelling would be required.

FSANZ has not developed a caffeine threshold below which FSSFs would be exempt from the 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 proposed approach is a more pragmatic way of achieving the same outcome as setting a threshold such as the 10 mg per serve suggested. 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 ergogenic effect. An exemption from the caffeine-related labelling requirements for caffeine itself, including a threshold limit, is therefore not appropriate or necessary.

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). Therefore, when used as an ingredient in a FSSF, these foods contribute minimal amounts of caffeine. The proposed approach is therefore 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 other foods containing chocolate, cocoa, decaffeinated tea or decaffeinated coffee.

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 significant amounts of caffeine to a FSSF compared to chocolate etc. This 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.

2.3.1.2 The proposed drafting changes

FSANZ is proposing to make the following changes to the draft variation.

The draft variation will 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 will 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.

See Item [10] of the Schedule to the revised draft variation at Attachment 1.

2.3.2 Labelling of individual portions in caffeine-containing FSSF

For the reasons stated in the 1st CFS, FSANZ proposed amending the Code to require an advisory statement using wording to the effect of 'contains caffeine' on the label of all FSSF containing caffeine, irrespective of the source or amount. For FSSF not required to bear a label under Standard 1.2.1, FSANZ proposed that the advisory statement would be required to be provided either in connection with the sale of the food or upon request.

This advisory statement is in addition to the proposed requirement for FSSF containing caffeine to be labelled with 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.' The warning statement was proposed in the 2nd CFS (FSANZ 2025, section 2.2.9.2).

For the reasons stated in that CFS, FSANZ proposed amending the Code to require small volume, solid and semi-solid FSSF (such as gummies and dissolvable strips) to be individually wrapped portions when the pieces require no further preparation and the bulk packet contains more than a total of 200 mg caffeine from any source. This proposed measure aligned with the findings of Proposal P1054, which found that individually divided and packaged small volume, highly caffeinated sports food products have a different risk characterisation to multiple pieces in undivided packaging because the total caffeine exposure is likely to be limited by the form of packaging. The labelling of these individual portions was not specifically discussed.

FSANZ received several comments on this aspect of the draft variation.

Although the proposed approach was supported by several submitters, others suggested it did not sufficiently address the risk posed by these products, particularly for younger children. A small number of submitters suggested the warning statements required on the outer packaging of FSSF should also be displayed on the individual portions to avoid inadvertent caffeine consumption. These comments are summarised below in Table 6.

Table 6 – Summary of issues – individual portion in caffeine-containing FSSF

Issue	Raised by	FSANZ response
P1056 has not examined the extent of the risk of caffeine overconsumption through confectionery-like FSSF by vulnerable sub-populations (e.g. small children) and how the risk should be managed.	NSWFA	After consideration of submissions, and for the reasons summarised in section 2.3.2.1 and 2.3.2.2 below, FSANZ is proposing to amend the draft variation to require a caffeine advisory statement on certain types of individual portions of FSSF to assist parents and caregivers to restrict children's access to these products.
Clarification is sought about whether a single serve of FSSF will be required to carry the warning statement to be on the individual package. If the individual packages are separated from the outer retail package, the consumer may not be aware of the risk.	DoHWA	See response above. FSANZ is proposing to require a caffeine advisory statement on individual portions to inform consumers about their nature as caffeinated products. The warning statement is not proposed to be required on the individual portions due to its length and prescriptive nature.
Clarification is sought as to whether individual packages require the proposed warning statement to be displayed on each package. The submitter states that they should.	ECU	See responses above.

2.3.2.1 Discussion

At the 2nd CFS, FSANZ noted that one of the factors contributing to the risk associated with small volume, high caffeine products, particularly for younger children, is that they can resemble confectionery. While parents and caregivers are responsible for ensuring that foods unsuitable for children, such as FSSF, are kept out of reach, FSANZ acknowledges there is a risk of inadvertent consumption of caffeinated FSSF if the individually wrapped portions are stored or used in isolation from the outer packaging and consumers are unaware of their caffeinated nature. This risk is increased in cases where they resemble non-caffeinated products, such as confectionery or muesli bars, and can be mistaken for them.

Due to children's low bodyweight, consumption of small volume, high caffeine products present a higher risk of acute toxicity (FSANZ 2025, SD1). FSANZ is aware of bulk packages of gummies available in the domestic market that resemble confectionery and contain 250-300 mg caffeine per gummy. Under amendments proposed in the 1st CFS, the maximum amount of caffeine that would be permitted in an individual portion of FSSF is 200 mg as a one-day quantity. However, this is still more than 5 times the safe consumption of 3 mg/kg bw/day for a 1–3 year old child (averaging 13 kg), and 3 times the safe consumption for a 4–8 year old child (averaging 22 kg; see 2nd CFS, SD1)(FSANZ 2025) in a single portion.

There is a foreseeable risk that, if individual portions of caffeinated FSSF are stored or used in isolation from the outer packaging, they could be inadvertently consumed or given to children due to a lack of awareness of their caffeine content, particularly where they resemble non-caffeinated products. To mitigate this risk, FSANZ considers that the caffeine advisory statement mandated on the outer label of these products should also be present on individual portions with a surface area of 30 cm^2 or greater. The caffeine advisory statement is intended to alert consumers, including parents or caregivers of young children, to the caffeinated nature of these products in the absence of outer packaging. This approach aligns with that for allergen labelling, which is mandated on individual portion packs that have a surface area of 30 cm^2 or greater to manage a similarly acute risk for a vulnerable subpopulation (allergic consumers).

The requirement for the caffeine advisory statement on the individual portion would only apply to those FSSF specified in paragraph 2.9.4—12(1)(c) of the revised draft variation. That is, it would only apply to individual portions in a ready to eat solid or semi-solid form (excluding powders), such as bars, chewables and dissolvable strips. FSANZ considers these forms of FSSF represent the greatest risk of inadvertent and/or over-consumption and that this approach is proportionate to the risk posed by these forms of FSSF.

FSANZ acknowledges there are other forms of caffeine-containing FSSF that could be sold in a multipack, such as concentrated or ready-to-drink liquids and pre-workout powders packaged in individual sachets. The advisory statement would not be required on the individual portion of these forms of FSSF however the outer package would still be subject to the advisory and warning statement requirements.

Liquids and powders would be subject to both the maximum 200 mg one-day quantity of caffeine and the 1% and 5% concentration limits specified in section 2.9.4—3(3). Ready-to-drink liquids in a multipack are likely to be fully labelled for retail sale. Concentrated liquids and pre-workout powders are less palatable unless prepared according to instructions are also less likely to resemble non-caffeinated general foods. FSANZ therefore considers the risk of inadvertent consumption of these products to be lower than for ready to eat solid or semi-solid FSSF that require no further preparation and are quite often small in volume.

The warning statement proposed for the outer packaging of caffeinated FSSF is not

proposed to be required on the label of individual portions. 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. FSANZ considers the caffeine advisory statement on the individual portion is sufficient to signify the caffeinated nature of these products and may encourage consumers to refer to the outer packaging, which carries the more detailed warning statement, for further information.

The costs associated with this risk management measure are expected to be minimal for suppliers of products in a bulk package that are not currently individually wrapped, as they will already be making labelling decisions at the point of re-packaging to meet the new requirement for individual packaging. There may be a small label change cost associated with this measure for bulk packaged products that already contain individually wrapped portions where the individual portions do not have an existing caffeine advisory statement. It is not possible to estimate the number of products this would impact.

2.3.2.2 The proposed drafting changes

FSANZ proposed the following in the draft variation at 2nd CFS:

When an FSSF meets each of the following criteria, section 2.9.4—12 will require the individual portions to be individually wrapped:

(a) The FFSF contains more than 200 mg caffeine in total, from any source.
(b) The FSSF is sold in packaging that includes individual portions of the food.
(c) One or more 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.

FSANZ is proposing the following changes to the draft variation.

Section 2.9.4—12 will set the following labelling requirements for FSSF to which that section applies.

(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 cm^2 or greater.

See Item [15] of the Schedule to the revised draft variation at Attachment 1.

2.4 Risk communication

2.4.1 Consultation

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

The release of this consultation paper is supported by a media release, updated website information and public notification via Food Standards News.

2.4.2 World Trade Organization (WTO)

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

There are not any relevant international standards regarding caffeine, however amending the Code to provide specific permission for the addition of caffeine to FSSF and prohibit its addition to other foods unless specifically permitted may have an effect on international trade. Therefore, notifications to the WTO under Australia and New Zealand's obligations under the WTO notifications were made at the 2nd CFS stage to enable other WTO members to comment on the proposed amendments. Revision notifications will be made for this consultation paper.

2.5 FSANZ Act assessment requirements

When assessing this Proposal and the subsequent development of a food regulatory measure, including developing the proposed revisions outlined in this consultation paper, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

2.5.1 Section 59 – Consideration of costs and benefits

This section summarises FSANZ's assessment of the costs and benefits of the Proposal.

FSANZ's assessment is that the direct and indirect benefits that would arise from the food regulatory measure developed or varied as a result of the Proposal outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

2.5.1.1 Background to the cost and benefit analysis

FSANZ is developing a Decision Regulation Impact Statement (DRIS) for this Proposal, which will be presented to the FSANZ Board with the Approval Report ahead of its consideration of whether to amend the Code. The DRIS will be submitted to the Office of Impact Analysis (OIA) for assessment against OIA guidance.

FSANZ did not develop a Consultation Regulation Impact Statement (CRIS) for this Proposal. The function of the CRIS was achieved by Supporting Document 5 (SD5) to the 2nd Call for Submissions (FSANZ 2025) and the statutory consultation that has been undertaken by the 1st CFS and the 2nd CFS. The OIA agreed with this decision and provided an exemption.[9]

The DRIS will be based on the analyses presented at the 2nd CFS (FSANZ 2025, SD5), and updated based on stakeholder comments to the 2nd CFS and this consultation paper.

The assessment of the costs and benefits for this consultation paper are based on the assessments for the 2nd CFS, and have been updated where the proposed amendments to the Code have changed (see section 2.5.1.2 below for updates to the cost and benefits).

[9] The OIA reference number for this Proposal is OIA24-07750

2.5.1.2 Costs of the Proposal

The food industry will incur costs to make impacted products compliant with the amended Code. The costs below include all costs of the proposed amendments for P1056 including those outlined in this consultation paper.

Potential costs for FSSF include:

- reformulation, where caffeine levels are over 200 mg
- relabelling, to update existing labels to meet new requirements
- repackaging, of a small number of impacted products (see below).

Repackaging would be required to individually package ready-to-consume solid or semi-solid FSSF that is sold in a multi-serve pack that contains a total amount of caffeine greater than 200 mg.

As outlined in section 2.3.2, individual packages will also require the advisory statement 'contains caffeine'[10], FSANZ does not expect this requirement will increase costs.

At the 2nd CFS, the total cost of reformulation and relabelling FSSF was estimated to be $3.1m to $6.2m. This cost will be reassessed for the DRIS and may change.

The cost of repackaging was unquantifiable at the 2nd CFS. FSANZ has not been able to quantify this cost (including any additional impact of amendments made to the proposal) with the information available for this analysis. The overall cost of repackaging is expected to be low. This is because few products are expected to be impacted.

Potential costs for non-FSSF products include:

- reformulation to remove added caffeine[11]
- relabelling beverages containing coffee that contain 200 mg caffeine or more per serving[12]

The total cost impact of removing added caffeine (including when guarana extract is a source of added caffeine (see section 2.2)) from general foods for retail sale is expected to be small. Less than 5 products were found in the FSANZ Branded Food Database that would be impacted.

FSANZ estimates the total cost of relabelling impacted coffee beverages would be less than A$100,000. FSANZ has estimated that less than 20 products would be impacted, based on analysis of products in the FSANZ Branded Food Database. The cost per product is expected to be between $3,500 to $4,350 per SKU (depending on the extent of changes required) based on the FSANZ label change cost model.

While most products already provide the information that would be required by the Proposal, analysing the labels of products found in the Branded Food Data shows that the text of voluntary labels differs from the warning statement proposed. Therefore, it has been assumed that all products will require relabelling to a certain extent.

All costs identified may be passed on to consumers. Some products may be withdrawn where the costs to make them compliant are not viable. This would have an impact on

[10] Unless an existing exemption for small surface area packaging applies
[11] Some products could be repositioned as a FSSF, resulting in relabelling costs instead of reformulation costs
[12] Exemptions apply to products that are not required to display a NIP

consumer choice.

No additional costs to government have been identified.

2.5.1.3 Benefits of the proposal

Updating the Code may provide businesses:

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

In consultation, some industry stakeholders stated that currently there are different interpretations of how the Code regulates caffeine, and greater 'clarity' would be beneficial (FSANZ 2025, Appendix 1).

For FSSF, regulatory certainty is likely to lower regulatory risk and may reduce costs and increase investment. For FSSF, businesses will benefit from certainty on:

- the ability to add caffeine
- the quantity that is allowed, and safe for consumers
- labelling requirements for caffeinated FSSF.

For general foods, businesses will benefit from certainty on:

- what foods caffeine can be added to
- approval pathway for new permissions (through the existing application process).

Greater certainty reduces the risk of inadvertent non-compliance, which can result in expenses related to product recalls (including the cost of having to dispose of recalled products) and damage to a business's reputation.

Consumers (as a collective) will experience health benefits from this proposal, as a result of reduced risk of over consumption of caffeine.

The proposal reduces risk, by:

- lowering the aggregate amount of caffeine in the food supply
- amending the Code to permit caffeine in FSSF at a level that balances the benefits of caffeine against its risks
- requiring information to be provided to consumers, in a consistent format.

Many consumers are also likely to value the information required on label given its potential to support the safe and appropriate use of these foods.

The proposed changes will benefit governments in Australia and New Zealand.

The proposal is expected to provide governments with more clarity and therefore is expected to improve the enforceability of the Code.

Government stakeholders claim that currently there is 'ambiguity' and 'uncertainty' on how the Code regulates caffeine, and that greater clarity is required in order for the Code to achieve the intent of the Code. Jurisdictions have claimed that the lack of clarity impacts on governments, impeding their ability limit the over-consumption of caffeine and therefore protect public health and safety.

Health benefits to consumers will flow through to governments as a result of less expenditure on healthcare.

2.5.1.4 Conclusion of cost and benefit analysis

FSANZ's assessment is that the benefits that would arise from the proposal most likely outweigh the associated costs, and therefore the proposal will lead to a net benefit to society. FSANZ's assessment is that the benefits identified above (including health benefits for consumers, the value of information provided to consumers, and regulatory certainty for industry) outweigh the cost identified above (including reformulating caffeinated FSSF and general foods with added caffeine, relabelling FSSF and some high caffeine coffee beverages, and repackaging some FSSF). FSANZ has not been able to quantify all the costs and benefits for this proposal. 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, which was also calculated for the 2nd CFS.

FSANZ has updated the break-even analysis presented at the 2nd CFS with the additional label change cost quantified above. The break-even analysis divides the quantified costs of the proposal (listed above) by the number of FSSF consumers. n the break-even analysis, a consumer has been defined someone who consumes a caffeinated FSSF daily (based on data from the 2023 FSANZ Consumer Insights Tracker).

While the additional cost relates to non-FSSF products, a consumer was chosen to model the break-even benefits because consumers are most likely to benefit due to the higher concentration of caffeine in FSSF.

The results of the updated break-even analysis shows that daily users of caffeinated FSSF will still only need to receive benefit of $1 to $2 per year for the benefits of the proposal to exceed the quantified costs. A proportion of the additional label change costs arising from the amended proposal are likely to impact non-FSSF consumers, which means that the break-even amount may be lower than estimated. FSANZ considers it likely that this benefit will be achieved, given that a significant number of consumers are expected to experience minor benefits from the change.

Therefore, in FSANZ view, the break-even analysis for FSSF consumers supports the conclusion that the overall proposal will lead to a net benefit to society.

2.5.1.5 Other measures

At the 1st CFS, FSANZ considered a range of measures that would be more cost-effective than a food regulatory measure developed or varied as a result of the proposal. FSANZ sought feedback on three possible measures at the 1st CFS (FSANZ 2022, section 3.1). Submitters broadly supported the development of a food regulatory measure (FSANZ 2025, section 2.2 onwards).

2.5.1.6 Any relevant New Zealand standards

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

2.5.1.7 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ has assessed the relevant scientific evidence on the risks to public health and safety arising from foods containing caffeine, as well as risk management measures currently in place such as maximum permitted levels of caffeine and advisory statements for certain foods. The assessment indicated that some risks exist to the health and safety of consumers (sections 2.2 and 2.3.1.2, 2nd CFS). 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 informed the proposed regulatory measures set out in the draft variation prepared following the consideration of submissions and the revised regulatory measures in this consultation paper. 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 (section 2.2 of this report, 2nd CFS).

Since the 2nd CFS, FSANZ has proposed additional labelling measures to mitigate public health and safety risks from consumption of high caffeine beverages containing coffee and wrapped individual portions of FSSF containing caffeine (sections 2.2.3 and 2.3.2 of this report, and in the revised draft variation at Attachment A).

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

Nutrition information relating to caffeine content and amount and warning and advisory statements would be required for a limited range of products that contain caffeine (see sections 2.2.7 - 2.2.9, 2nd CFS (FSANZ 2025) and sections 2.2.3 and 2.3.2 of this report). These requirements would assist consumers to make informed choices.

2.5.2.3 The prevention of misleading or deceptive conduct

FSANZ has not identified any relevant issues.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ's risk analysis considered the best available scientific information. FSANZ had regard to prior assessments regarding caffeine permissions in the Code (Attachment 1, 1st CFS) (FSANZ 2022), as well as P1054 (FSANZ 2020). Additional information was sought from stakeholders through the 1st and 2nd CFS. FSANZ has conducted a safety assessment of caffeine (SD1), Dietary Intake Assessment (SD2), Social Science Literature Review (SD3), Assessment of Caffeine Performance (SD4) and Cost and Benefit Analysis (SD5)(FSANZ 2025).

- **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 section 1.4.4, 2nd CFS for provisions in other countries.

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

As detailed in the Costs and Benefits Analysis (FSANZ 2025, SD5), amending the Code as proposed may provide the food industry:

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

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

Domestically produced products have a reputation as being 'clean' and safe in international markets, which enables domestic manufacturers to capture more of the export product market (IBISWorld 2023). It is expected that this proposal will further improve this reputation. See SD5, 2nd CFS for details.

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

FSANZ has not identified any issues to date.

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

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

- Ministerial Policy Guideline – Regulatory Management of Caffeine in the Food Supply
- Policy guideline – Addition to Food of Substances other than Vitamins and Minerals
- 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, when preparing the draft variation and in developing the proposed amendments summarised in this paper. FSANZ considers that each amendment addresses each Policy Guideline.

3 Draft variation

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

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

3.1 Transitional arrangements

The revised draft variation proposed by FSANZ provides transitional arrangements. These arrangements are the same as those set out in the draft variation proposed at the 2nd

CFS. That is, 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. See section 3.1.1, 2nd CFS (FSANZ 2025) for further discussion.

4 References

Food Chemicals Codex (2018) *Food Chemicals Codex 12*. p182.

Food Standards Australia New Zealand (FSANZ) (2019) Report - Pure and highly concentrated caffeine products. FSANZ, Canberra. Available online at: https://www.foodstandards.govt.nz/sites/default/files/2023-10/CaffeineReport2019.pdf

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FSANZ (2020). Proposal P1054 – Amendment Report. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/P1054

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FSANZ (2025) Proposal P1056 – 2nd Call for Submissions. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/2025-03/P1056%202nd%20CFS.pdf

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USFDA (2018) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-highly-concentrated-caffeine-dietary-supplements.

Attachments

A. Draft variations to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement
C Draft variations to the Australia New Zealand Food Standards Code proposed at the 2nd CFS

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

Food Standards (Proposal P1056 – Caffeine review) Variation

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

Dated [To be completed by the Delegate]

[Insert name of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

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

1 Name

This instrument is the *Food Standards (Proposal P1056 – Caffeine review) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

4. Transitional arrangements

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

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

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

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

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

Schedule

Standard 1.1.1 Structure of the Code and general provisions

[1] Paragraph 1.1.1—10(5)(g)

Repeal the paragraph, substitute:

(g) if the food is for retail sale—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.

Attachment B – Draft Explanatory Statement

DRAFT 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). that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

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

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

2. Variation will be a legislative instrument

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

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

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

part of those food laws.

3. Purpose

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

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

5. Consultation

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

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

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

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

6. Statement of compatibility with human rights

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

7. Variation

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

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

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

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

Clause 4 provides a transitional arrangement.
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 two-year 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 will 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]** propose amendments to 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] would amend paragraph 1.1.1—10(5)(g) by repealing the paragraph and substituting it with an amended paragraph 1.1.1—10(5)(g).

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 prohibition will be repealed.

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

If approved—the amended paragraph would prohibit 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 will define what is a prescribed caffeine product for the purposes of paragraph 1.1.1—10(5)(g). The definition will list 1,3,7-trimethylxanthine (ie, caffeine) and guarana extract as prescribed caffeine products. See **Item [5]** of the Schedule below.

The effect of the above will be to prohibit 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.

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

Subsection 1.1.1—10(6) prohibits 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.'.

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

Item [3] would insert an example after subsection 1.1.1—10(7) and a new provision 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 example inserted after subsection 1.1.1—10(7) relates 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) would prohibit a food for retail sale from having caffeine as an ingredient or a component—unless expressly permitted by the Code. Subsection 1.1.1—10(7) would provide 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 proposed example will explain:

- 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) will state that subsection 1.1.1—10(7) does not apply to 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).

Standard 1.1.2 – Definitions used throughout the Code

Items [4] to [6] of the Schedule to the variation proposes an amendment to Standard 1.1.2 of the Code.

Standard 1.1.2 sets out definitions of terms used in the Code—unless the contrary intention is expressed elsewhere in the Code.

Item [4] would amend paragraph (e) of the definition of *warning statement* in subsection 1.1.2—2(3).

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

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

This amendment is consequential to the amendment proposed in **item [14],** which would amend existing requirements in paragraph 2.9.4—4(1)(a) for warning statements on Formulated supplementary sports foods; and add a new requirement for a warning statement on such foods (see below for details).

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

Item [5] would add a new definition of *prescribed caffeine product* to subsection 1.1.2—2(3).

The new definition will state that reference in the Code to a prescribed caffeine is a reference to one or both of the following: 1,3,7-trimethylxanthine (ie, caffeine) and guarana extract.

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

Item [6] would add a new definition of *high caffeine coffee beverage* to subsection 1.1.2—2(3).

The new definition will state that a reference in the Code to a *high caffeine coffee beverage* is a reference to a food for retail sale that meets each of the following criteria.

(a) It is a beverage
(b) It is in a package
(c) It bears a label with a nutrition information panel
(d) It contains coffee
(e) It contains no less than 200 mg caffeine per serving
(f) It is not a formulated caffeinated beverage or a formulated supplementary sports food

This amendment is consequential to the amendment proposed in **items [7]** and **[17]** below.

<u>Standard 1.2.1 – Requirements to have labels or otherwise provide information</u>

Items [7] and [8] of the Schedule to the variation propose amendments to Standard 1.2.1 of the Code.

Standard 1.2.1 sets out when a food for sale must *bear a label* or have other information provided with it, and sets out what information must be provided in this case.

Items [7] and **[8]** would 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, must bear a label (as defined by the Code) with the information referred to in subsection

1.2.1—8(1) unless certain exemptions apply.

Item [7] would amend subsection 1.2.1—8(1).

The amendment would repeal paragraph 1.2.1—8(1)(za) and substitute it with an amended paragraph (za) and a new paragraph 1.2.1—8(1)(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) will list 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) defines what is an average quantity of a substance in a food for the purposes of the above. It means the average 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 consequential to the amendment proposed in **item [17]** below.

Item [8] would repeal subsection 1.2.1—8(3) and substitute it with an amended subsection 1.2.1—8(3) that includes a reference to subsection 2.10.4—3A(2).

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. At present, this information is the warning statements and declarations made in accordance with sections 1.2.3—3 and 1.2.3—4.

The amendment will also require the advisory statements required by subsection 2.10.4—3A(2) to be included on the label of the individual portion packs.

This amendment is also consequential to the amendment proposed in **item [17]** below.

Standard 1.5.1 – Novel foods

Items [9] of the Schedule to the variation would amend Standard 1.5.1 of the Code, by inserting new subsection 1.5.1—3(3) into that Standard.

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 this purpose.

New subsection 1.5.1—3(3) would provide that, despite any other provision of the Code (such as paragraph 1.1.1—10(6)(k), any express permission in the Code for the purposes of that paragraph, or subsection 1.1.1—10(7)) , 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 has been listed in section S25—2 of the Code as a permitted novel food and any and all 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 caffeine

that is, part of or derived from a novel food. Premarket assessment and approval as a novel food will also be required.

Standard 2.9.4 – Formulated supplementary sports foods

Items [10]-[15] of the Schedule to the variation would 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.

Item [10] would amend section 2.9.4—2, which lists definitions of terms used in Standard 2.9.4.

Amended section 2.9.4—2 will define what is caffeine for the purposes of subparagraphs 2.9.4—4(1)(iii) and (iv) and subsection 2.9.4—11(1). It will 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.

Item [11]-[13] propose amendments to section 2.9.4—3.

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

Item [11] would amend subparagraph 2.9.4—3(1)(c)(ii) by repealing the subparagraph and substituting it with an amended subparagraph (ii) and a new paragraph 2.9.4—3(1)(d).

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 paragraph 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) would refer to ‘caffeine’ as a substance that formulated supplementary sports food may contain.

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

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

Item [12] would amend paragraph 2.9.4—3(2)(b) by repealing the paragraph and substituting it with an amended paragraph 2.9.4—3(2)(b) and a new paragraph 2.9.4—3(2)(c).

Subsection 2.9.4—3(2) sets a compositional requirement for a formulated supplementary sports food. It lists the substances that food must not contain, in a *one-day quantity*.

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

Amended paragraph 2.9.4—3(2)(b) is identical to the existing paragraph 2.9.4—3(1)(c)(ii) 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.'.

If approved, the effect of the amendment proposed in **item [12]** would be that a formulated supplementary sports food must not contain, in a one-day quantity, more than 200mg 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.

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

New subsection 2.9.4—3(3) would set a new compositional requirement for a formulated supplementary sports food. It will provide that 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 sub-paragraph 2.9.4—3(2)(c), which prohibits a formulated supplementary sports food from containing, in a one-day quantity, more than 200mg of caffeine in total from any source.

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

Item [14] proposes to 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 a labelling requirement and an information requirement set by the Code and that applies to that food.

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

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

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

Warning statement is defined in Standard 1.1.2 (see also **item [4]** above).

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

The warning statement itself is the same, but that statement would only be required if the formulated supplementary sports food does not contain caffeine (as defined by section 2.9.4—2 – see **Item [10]**).

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

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

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

A note would be inserted after subparagraph 2.9.4—4(1)(a)(iv) to advise readers that 'Section 2.9.4—2 defines caffeine for the purposes of this subparagraph'.

These new requirements are related to the proposed amendments to section 2.9.4—3 (see **items [11]** – **[13]** above).

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 has to be renumbered as a consequence of the other amendments proposed to paragraph 2.9.4—4(1)(a) above

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

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

Item [15] would amend Standard 2.9.4 by adding new sections 2.9.4—11 and 2.9.4—12.

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

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

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

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

New subsection 2.9.4—11(2) specifies where the information required by new subsection 2.9.4—11(1) must be located in the nutrition information panel. That is -

- 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.

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 a labelling requirement and an information requirement set by the Code and that applies to that food.

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

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

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

New section 2.9.4—12 sets packaging, labelling and information requirements for formulated supplementary sports food that contains caffeine and comprises of small separate 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 a labelling requirement, packaging requirement or an information requirement set by the Code and that applies to that food.

New subsection 2.9.4—12(1) will provide 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 will be provided after subsection 2.9.4—12(1): 'A formulated supplementary sports food sold in the form of chewables or dissolvable strips that contain caffeine'.

New subsection 2.9.4—12(2) will require the outer package of the formulated supplementary sports food must have an advisory statement to the effect that the food contains caffeine. This is the advisory statement is required by subparagraph 2.9.4—4(1)(a)(iv)(A). The new subsection will require this statement to appear on the outer package of the formulated supplementary sports food.

New subsection 2.9.4—12(3) to (6) will set requirements for an individual portion that is included in the packaging of the formulated supplementary sports food and which meets the each of the criteria set out in paragraph 2.9.4—12(1)(c). That is, the individual portion is in a solid or semi-solid form, is not designed for individual sale, and no further preparation required before its consumption.

New subsection 2.9.4—12(3) will require the individual portion to be separately packaged.

New subsection 2.9.4—12(4) will provide that the individual portion must not contain more than 200 mg caffeine in total, from any source.

New subsection 2.9.4—12(4) will require the 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.

New subsection 2.9.4—12(5) will require each individual portion which meets the criteria set out in paragraph 2.9.4—12(1)(c)

The intent of proposed 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 [16] and [17] of the Schedule to the variation would amend Standard 2.10.4 of the Code.

Standard 2.10.4 sets out compositional requirements for other foods including coffee, tea, chocolate, cocoa, gelatine and peanut butter.

Item [16] would amend section 2.10.4—2.

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

The amendment would insert a note referring to the definition of *high caffeine coffee beverage* provided by subsection 1.1.2—2(3). See **item [7]** above.

Item [17] would insert a new section 2.10.4—3A into Standard 2.10.4 to set labelling requirements for high caffeine coffee beverages.

New section 2.10.4—3A would set - 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) would provide the declaration of average quantity required by the labelling provisions is a declaration in the nutrition information panel of the average quantity of caffeine, expressed in milligrams, in:

- A serving of the food; and
- A unit quantity of the food

The labelling provisions are those set out in Standard 1.2.1.

New subsection 2.10.4—3A(2) would provide the advisory statements required by the labelling provisions 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.'

If approved, the effect of the proposed amendment in **item [16] and item [17]** would be that where food is a high caffeine coffee beverage—that food will be required to bear a label that provides the average quantity of caffeine in the nutrition information panel in accordance with Standard 1.2.1 for the food and a prescribed advisory statement.

The intent of this proposed amendment is when caffeine from coffee is over the amount where adverse effects can begin, to provide consumers with the amount of caffeine in the product and alert consumers to the fact that the food contains caffeine at a level that is not suitable for pregnant or breastfeeding women and children in alignment with the P1056 safety assessment.

Attachment C – Draft variations to the Australia New Zealand Food Standards Code proposed at the 2nd CFS

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.