19 December 2022
[223–22]

1st Call for submissions – Proposal P1056

Caffeine review

FSANZ has assessed a proposal to review permissions for caffeine in sports foods and in the general food supply and consider the risk caffeine poses to sensitive sub-populations. Pursuant to section 72 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist further consideration of the proposal.

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

All submissions on applications and proposals will be published on our website. 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 as soon as possible after the end of the submission period.

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

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

Submissions should be made in writing and be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made by emailing your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 13 February 2023

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

Questions about making 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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Supporting documents

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

SD 1 Safety assessment
SD 2 Dietary intake assessment
SD 3 Social science assessment
SD 4 Assessment of caffeine and sports performance

Executive summary

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

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

In completing P1054, Food Standards Australia New Zealand (FSANZ) undertook to prepare this separate proposal to consider whether additional measures are required in relation to the regulation of caffeine in the Australian and New Zealand food supply in order to protect public health and safety. In particular, the proposal is examining:

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

Currently there are express permissions in the Code to add caffeine to cola-type drinks and formulated caffeinated beverages (FCBs). Foods for retail sale are also permitted to contain caffeine that is present naturally, in minimal amounts, such as coffee, teas and chocolate. FSANZ is not proposing to amend the permissions for cola-type drinks and FCBs or naturally occurring caffeine under this proposal.

The proposal is being assessed under the Major Procedure provisions in the *Food Standards Australia New Zealand Act 1991* which require two calls for submission (CFS) processes. This first CFS seeks submissions from interested parties on FSANZ's assessment and preliminary conclusions. If, after considering all submissions, FSANZ decides to prepare a draft variation, a second CFS will be issued to seek comment on FSANZ's proposed regulatory approach, including that variation.

FSANZ has undertaken a safety assessment (SD 1), dietary intake assessment (SD 2), social science assessment (SD 3) and an assessment of caffeine and sports performance (SD 4). These assessments examined the risk posed by caffeine consumption in various sub-populations, intakes of caffeine from foods, consumer understanding and/or behaviour regarding caffeine in both general foods and sports foods and the effect of caffeine on aerobic exercise performance. These SD's informed the development of the proposed risk management measures.

FSANZ's safety assessment concluded that chronic (habitual), moderate consumption of caffeine in foods in adults is safe at up to 400 mg/day. It also concluded that acute (single dose) intakes of caffeine over 210 mg/serve (approximately 3 mg/kg of bodyweight) is associated with adverse health effects. These effects include increase in blood pressure, plasma catecholamines and anxiety at lower intakes, leading to more serious effects such as tachycardia, ventricular arrhythmia or seizures at acute consumption levels.

FSANZ's dietary intake assessment found that caffeine was consumed by 87% of Australians and 93% of New Zealand adults on day one of national nutrition surveys. Estimated usual intakes for the population groups assessed indicated that no or few children and adolescents exceeded the recommended maximum safe levels. Up to 6% of adults had a caffeine intake that exceeded the recommended maximum safe levels.

FSANZ notes that the majority of caffeine consumption occurred through non-alcoholic beverage consumption and not through sports foods, however these data do not reflect changes in the sports food and beverage market since the most recent Australian and New Zealand national nutrition surveys. The risk to public health and safety, however, lies predominantly with the portion of the population who exceed, or come close to exceeding the maximum safe intake of caffeine. It follows that the risk is increased for those who regularly consume sports foods with added caffeine. Research from Australia and New Zealand suggests that sports foods consumption is also no longer limited to athletes. Therefore proposed regulatory measures for sports foods, or more precisely FSSF, must take into account the safety and suitability of caffeine consumption by the general population.

The above informed FSANZ's risk management, which considers three possible options:

1. Status quo (no changes to the Code)
2. Status quo combined with non-regulatory approach
3. Hybrid mix of regulatory and non-regulatory approaches

Option 3 is the preferred approach, with the preferred measures being:

- the introduction of a new express permission to add caffeine to FSSF, and
- an express prohibition on the addition of caffeine to foods for retail sale other than those that have a specific permission i.e. currently cola-type drinks and formulated caffeinated beverages (FCBs). This measure would have no impact on the current ability under the Code to add caffeine-containing foods to other foods, for example adding coffee or chocolate to a cake or confectionery.
- the inclusion of the non-regulatory options outlined in option 2 (section 3.1 below).

Based on the safety data for both chronic and acute consumption, as well as consideration of the demonstrated ergogenic benefit of caffeine and existing permissions in international regulations and set by peak sporting bodies, FSANZ proposes to explicitly permit in a FSSF, total caffeine up to a maximum of 200 mg in a one day quantity in conjunction with appropriate labelling requirements. This would mean that a consumer using a FSSF as directed on the label may consume a maximum of 200 mg total caffeine in one day from a single serve or through multiple serves of that FSSF, subject to the total amount of caffeine in a serving. In conjunction with the mean caffeine intake from all other general food sources, total caffeine intake is not expected to exceed the recommended maximum daily limit of 400 mg/day for consumers who are using FSSF to support their increased dietary requirements. Such an intake is considered safe and consistent with the intended purpose and the Code's definition of FSSF.

The proposed one-day quantity for caffeine in FSSF would also provide an amount that has a demonstrated ergogenic benefit informed by a scientific assessment. The setting of a one-day quantity for caffeine added to a FSSF is consistent with the permissions for added substances already contained in Standard 2.9.4 – Formulated Supplementary Sports Foods. This approach recognises that FSSF are special purpose foods, and in the case of FSSF, are '*a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals*.' The one-day quantity also provides certainty to FSSF manufacturers and enforcement agencies, allowing for product innovation and ready identification of non-compliant products.

The express prohibition on the addition of caffeine to other foods is based on ensuring safety for consumers. This approach recognises that caffeine is a substance that has maximum safe daily intake recommendations, which vary depending on age and population group. Should food businesses wish to add caffeine to other foods, an application could be made to FSANZ to amend the Code. The current regulation of caffeine in cola-type drinks and FCBs remains unchanged under option 3. It is also proposed that under option 3, the P1054 variation relating to pure and highly concentrated caffeinate products is removed as it will no longer be required.

FSANZ considers the proposed new express permission for caffeine in FSSF, the ongoing express permission to add caffeine to cola-type drinks and FCBs and a new prohibition on the addition of caffeine to all other foods, will reduce the risks to consumers.

Questions submitters may like to consider with regard to the proposed approach are at Sections 3.7 and 3.9 of this report. Information received in submissions and further assessment will inform our decision on whether to prepare a draft variation and if so, on the content of that draft variation.

1 Introduction

1.1 The proposal

Food Standards Australia New Zealand (FSANZ) prepared this proposal on 12 December 2020 to 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, the proposal is examining caffeine in Formulated Supplementary Sports Foods (FSSF) and other foods in the general food supply, and the extent of the risk posed to sensitive sub-populations by caffeine in those foods and whether and how any such risk should best be managed. Sensitive sub-populations are groups of people who are at greater risk from exposure to a substance due to a characteristic they have, such as infants and pre-schoolers, children, pregnant women and people with chronic conditions.

1.2 Reasons for preparing the proposal

Proposal P1056 was prepared following consideration of Urgent Proposal P1054 – Pure and highly concentrated caffeine products. P1054 was declared as an Urgent Proposal under section 95 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act). The Urgent Proposal P1054 was prepared to prohibit the retail sale of pure and highly concentrated caffeine products due to the unacceptably high risk for consumers and a need to act quickly to protect public health and safety.

In December 2019, for the reasons detailed in the P1054 Final Consideration Report (FSANZ 2020) the FSANZ Board approved a variation to the Australia New Zealand Food Standards Code (the Code) to prohibit the retail sale of pure and highly concentrated caffeine products. The approved variation imposed a prohibition on a food for retail sale, unless expressly permitted by the Code, being a food in which caffeine is present in a concentration of:

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

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

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

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

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

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

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

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

1.2.1 Formulated Supplementary Sports Foods (FSSF)

FSSF are regulated by Standard 2.9.4 – Formulated Supplementary Sports Foods. Caffeine is a component of some FSSF, however there is no express permission for caffeine to be added to a 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 considers it prudent to consider the issue of caffeine in FSSF under the auspices of P1056 rather than P1010, to expedite any risk management measures.

1.3 Procedure for assessment

The proposal is being assessed under the Major Procedure as set out in the FSANZ Act. The Major Procedure includes two calls for submission (CFS) documents.

This first CFS seeks comment from interested parties on FSANZ's assessment and preliminary conclusion about whether or not to prepare a variation to the Code and FSANZ's preferred approach.

The second CFS will be issued if, after considering submissions received in response to the first CFS, FSANZ decides to prepare a draft variation to the Code. The second CFS will set out FSANZ's proposed regulatory approach, including the draft variation to the Code.

1.4 Sources of caffeine

Chemically, caffeine (1,3,7-trimethylxanthine) is a naturally occurring alkaloid that is found in varying quantities in the beans, leaves and fruits of more than 60 plants. It has a long history of human consumption. Some common sources of naturally occurring caffeine are the many plants from the *Rubiaceae* family of flowering plants, most notably arabica coffee (*Coffea arabica*) and robusta coffee (*Coffea canephora*), the tea plant (*Camellia sinensis)* and the Cocoa tree (*Theobroma cacao*).

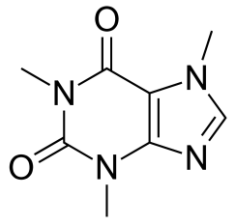
Where caffeine is added to foods as a permitted ingredient, it may be added as the extract from a plant (such as guarana) or as the chemically synthesised or purified form. The chemical and physical properties of caffeine are summarised in Table 1. Food chemicals codex has published a specification for caffeine (FCC 2018). The National Center for Biotechnology Information has published a Compound Summary for caffeine (NCBI 2022).

When plant sources of caffeine are prepared as food ingredients, they can be intentionally concentrated and standardised to a range of caffeine percentages, for example ranging from 2% to 20% caffeine. Some plant sources of caffeine, whether the whole plant or an extract from a plant source, may meet the definition of a novel food in the Code and require a pre-market assessment before they can be added to food irrespective of the purpose of addition to food.

P1056 is considering the addition of caffeine to foods, where permitted, regardless of the source (i.e. synthetically produced or from a plant source such as guarana extract).

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

Table 1: *Chemical and physical properties of caffeine*

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

1.5 The current standards

A representative timeline of major reviews and amendments to the Code in relation to caffeine is in Attachment 1.

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.

1.5.1 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.

1.5.2 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 1.5.2.1 to 1.5.2.6 below.

This proposal will have no impact on the sale of coffee, teas and chocolate that naturally contain caffeine, as defined in Standard 2.10.4 – Miscellaneous standards for other foods. Subsection 1.1.1—10(7) of Standard 1.1.1 allows for the presence of caffeine by natural occurrence in a compliant food or ingredient (such as coffee, tea or chocolate).

This proposal will also have no impact on the current ability under the Code to add compliant caffeine-containing foods to other foods, for example adding coffee or chocolate to a cake or confectionery. Such foods are included in types of foods included as sources of caffeine in the Dietary intake assessment (SD 2).

Caffeine can have more than one purpose when added to food. For example, when added for a physiological purpose, it is not being used as a food additive, processing aid or nutritive substance. There is an express permission under Standard 2.6.4 – Formulated caffeinated beverages to add the substance caffeine, without any regulatory purpose attributed to the added caffeine (such as *used as a food additive*). As noted in Section 1.4 above, this addition may be as synthetically produced caffeine or as caffeine contained in a plant extract such as guarana.

1.5.2.1 Processing aids

Paragraph 1.1.1—10(6)(c) 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.

1.5.2.2 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 GMP levels. The entry for 'Permitted flavouring substances' in tables to S16—2 specifically excludes caffeine. Therefore, any food categories in the table to section S15—5 allowing 'additives at GMP' or 'Permitted flavouring substances' are not permitted to contain caffeine within any flavouring preparation added to these food categories.

1.5.2.4 Nutritive substances

Paragraph 1.1.1—10(6)(b) of Standard 1.1.1 requires that, unless expressly permitted, a food for sale must not have as an ingredient or component a substance that was *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.

1.5.2.5 Novel foods

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

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 (section 1.1.1—10(6)). There are no such permissions for caffeine or foods containing caffeine in the Code.

1.5.2.6 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, from any source.

1.5.3 Labelling requirements relating to caffeine

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

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

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

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

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

1.5.4 The Therapeutic Goods Administration

Regulation of foods and medicines falls under separate legislated frameworks commensurate with the intended use and potential risks that those products pose to public health and safety. In Australia, the Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Aged Care and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products whereas 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, and the provisions of the FSANZ Act and the Code do not apply. For further background, refer to Section 2.2 of the Amendment Report for P1054 – Pure and highly concentrated caffeine products (FSANZ 2020).

Standard 2.9.4 of the Code will continue to regulate FSSF.

1.5.5 Food Imported into Australia from New Zealand

The Trans-Tasman Mutual Recognition Arrangement provides that food may be imported into Australia from New Zealand and sold in Australia provided it complies with the New Zealand food law. It is also exempt from inspection under the Imported Food Control Act. New Zealand food law includes the *New Zealand Supplemented Food Standard 2016*.

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

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

1.5.6 International permissions

The U.S. Code of Federal Regulations (CFR) enforced by the US Food and Drug Administration (US FDA) has a specific permission for caffeine as a Generally Regarded as Safe (GRAS) substance that can be added to cola-type drinks at a level up to 0.02% (200 mg/kg(L)) (USFDA 2020)). It is understood that this GRAS permission is given for its use as a flavouring substance, but it is not explicitly stated as such. It is noted that the US Food Chemicals Codex specification for caffeine lists its function as a flavouring agent.

Europe also permits caffeine as a flavouring substance (or as a stimulant when used for other purposes) as detailed in the European Commission list of flavouring substances search page (European Commission 2020). The EC flavouring number is 16.016. The EU regulation 2018/1482 (European Commission 2018) relates to specific permissions for caffeine addition to food. This contains a maximum level of 150 mg/kg for the food category 14.1 (non-alcoholic beverages). There are other permissions for the use of caffeine as a flavouring in other food categories being: dairy products and analogues (70 mg/kg), edible ices (70 mg/kg) and confectionery (100 mg/kg). Caffeine is also a flavouring with the Council of Europe, with flavouring number 11741.

The levels of use of caffeine as a flavouring in cola-type drinks is therefore similar in Australia and New Zealand, with a MPL of 145 mg/kg compared to 200 mg/kg in the US and 150 mg/kg in Europe. There is no consistent approach to regulation across the countries as

outlined in Attachment 2.

2 Summary of the assessment

2.1 Safety assessment

Full details of the safety assessment, with references, are in SD1.

2.1.1 Pharmacokinetics

Caffeine is rapidly and completely absorbed, and widely distributed in the body. The half-life is in the range 3 to 7 hours. Caffeine is metabolised primarily in the liver by cytochrome P450 1A2 (CYP1A2).

In pregnant women, the half-life of caffeine increases to approximately 10 hours by 17 weeks of gestation and up to 18 hours by the end of pregnancy, resulting in increased exposure to caffeine for both mother and foetus. Caffeine crosses the placenta by passive diffusion and both the foetus and placenta lack enzymes to metabolise caffeine. Milk:serum concentration ratios ranging from 0.52 to 0.81 have been reported for lactating women.

The half-life of caffeine in neonates is much longer than in adults, at up to 100 hours, due to immaturity of the CYP1A2 enzyme system. The system then matures rapidly, and caffeine clearance reaches or exceeds adult levels by 5 to 6 months of age.

2.1.2 Pharmacodynamics

The effects of caffeine are mediated through adenosine receptor antagonism at plasma concentrations achieved through normal dietary intake levels. Antagonism of adenosine receptors promotes the release of several neurotransmitters in the brain associated with the positive effects of caffeine, including glutamate, serotonin, acetylcholine, noradrenaline, and dopamine. Other mechanisms of action such as phosphodiesterase inhibition, GABA (gamma-aminobutyric acid) receptor modulation and activation of ryanodine-sensitive calcium channels become more relevant at toxic levels of intake.

Caffeine has been reported to interact with a range of medicines. For example, caffeine is contraindicated in pregnant women taking phenobarbital, because there is evidence that the combination of caffeine and phenobarbital is teratogenic, although neither is a significant human teratogen alone. Potential for interactions with prescription medicines should be managed by the medical care provider and in the medicine product information.

2.1.3 Acute (single dose) consumption of caffeine

Single intakes of caffeine of up to 210 mg (approximately 3 mg/kg bw) are not generally associated with any adverse effects. Above that dose, caffeine intake is associated with an increase in blood pressure, plasma catecholamines and anxiety (see table 2 below). FSANZ and other agencies, such as the European Food Safety Authority (EFSA), US FDA and the Institute of Medicine have previously identified 400 mg/day as safe for most adults. At or above 1200 mg more serious effects such as tachycardia, ventricular arrhythmia or seizures may develop, and urgent medical attention may be required. Death of an adult has been reported following a single dose of 3000 mg but is more commonly associated with doses of around 5000 to 10,000 mg caffeine. The direct cause of death in caffeine poisoning is usually ventricular fibrillation.

Relative to adults, caffeine poses a higher risk of acute toxicity in infants and small children due to their low bodyweights. Internationally, infants and toddlers are at high risk of morbidity and mortality from acute caffeine poisoning, and data from poison centres in Australia and New Zealand indicate that infants and toddlers are over-represented among calls related to acute caffeine exposure. FSANZ obtained data from Australian and New Zealand poisons information centres covering various periods (VIC & NZ 2015 - 2021, NSW 2015 - 2019). This showed that of all calls relating to instances of caffeine over-consumption, 3% are related to infants aged 4 weeks to 1 year (n=37), 28% toddlers aged 1 to 4 years (n=365) and 12% children aged 5 to 14 years (n=156). Of those presenting at or referred to hospitals, on average 0.1% (n=1), 2.9% (n=37) and 7.2% (n=92) are infants, toddlers and children respectively. Caffeine exposure of infants and toddlers is often accidental but may be malicious.

In this report, safe caffeine consumption for adults is stated as 400 mg/day, which is based on a 70 kg adult consuming 5.7 mg/kg bodyweight per day (bw/day). For other population groups, the safe amount is stated in 'mg/kg bw/day' due to the wider variation of body weights in these groups compared to the adult population.

Table 2: *Acute effects of caffeine in adults*

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

[a] FSANZ (2000); [b] USFDA (2018) ; [c] EFSA (2015)

2.1.4 Chronic (habitual) consumption of caffeine

2.1.4.1 Adult population, excluding pregnant and lactating women

Chronic moderate consumption of caffeine at up to 400 mg/day (5.7 mg/kg bw/day based on a 70 kg bodyweight) is not associated with significant adverse effects in the general adult population. This is based on extensive epidemiological evidence, including systematic reviews and meta-analyses.

Caffeine consumption is typically self-limiting and is generally considered to have little potential for abuse. That is, consumers generally learn to regulate their intake to achieve the beneficial effects of caffeine while avoiding the adverse effects.

Evidence from premature infants and psychiatric patients indicates that chronic high consumption of caffeine does not have adverse physical effects. Protracted use of extremely high doses of caffeine[1] in premature infants, as therapy for apnoea of prematurity, has been found to have no adverse physical or psychological sequelae up to 11 years later. In addition, psychiatric patients typically consume seven times as much caffeine as the general population, and although this level of consumption may have adverse psychological effects in some psychiatric disorders, there is a lack of evidence of adverse physical effects.

2.1.4.2 Pregnant women

Findings of a systematic review with dose-response meta-analysis show positive associations between caffeine consumption and miscarriage, stillbirth, preterm delivery, low birthweight and small for gestational age (SGA) infants. The authors were not able to identify a threshold for these adverse effects, but the associations are generally modest within the range of usual dietary intake, and the results suggest that a maximum intake of 200 mg caffeine/day is acceptable for pregnant women.

2.1.4.3 Lactating women

There is very little information on the effects of caffeine exposure via breastmilk on infants and insufficient information to permit derivation of a numerical Health-Based Guidance Value.

2.1.4.4 Children

The FSANZ Expert Working Group on the safety aspects of dietary caffeine (FSANZ 2000), EFSA (2015) and BfR (2019), have previously recommended that intakes in children not exceed 3 mg/kg bw/day. The FSANZ Expert Working Group based this value on increased anxiety at that level.

A recent systematic review also reported negative effects of caffeine in children at moderate (~3 mg/kg bw/day) and high (~5 mg/kg bw/day) intakes including alteration of the sleep cycle and alterations in emotional states including anxiety and depression. EFSA identified a reference point of 1.4 mg caffeine/kg bw/day for sleep disturbance in children. The American Academy of Pediatrics discourages the use of caffeine by children and adolescents due to the adverse effects of sleep disturbance on academic performance.

2.1.4.5 Adolescents

There is a lack of new information on which to base a quantitative estimate of safe levels of caffeine intake for adolescents. Caffeine clearance in adolescents is likely to be at least that of adults, so the recommended maximum level for adults (i.e. 5.7 mg/kg bw/day) is also applicable to adolescents.

2.1.4.6 Athletes

Caffeine has positive effects on physical exertion, and the purported risks of dehydration or acute mountain sickness from the diuretic effect of caffeine appear to be unfounded. In fact, caffeine may be more beneficial than harmful at high altitude. However, studies and reviews conducted overseas have concluded that athletes are at elevated risk of caffeine toxicosis. Reasons include misleading labelling of sports supplements, failure to follow the

[1] Loading dose of 80 mg/kg bw/day followed by maintenance dose of 20 mg/kg bw/day, at a stage of development at which the elimination half-life is 100 h

recommended daily dose, deliberate or inadvertent 'stacking' by consuming caffeine from multiple sources, and a general lack of appreciation of the risks of high caffeine consumption. Caffeine may exacerbate body dysmorphia in bodybuilders. The extent to which these issues affect risk to athletes in Australia or New Zealand is not clear.

A maximum level of 400 mg/day is considered safe for athletes.

There is a lack of information on potential interactions between caffeine and the other chemicals commonly included in energy drinks and other sports supplements.

2.1.4.7 Other potentially sensitive sub-populations

Caffeine consumption is generally self-limiting in adults, due to consumers' familiarity with its adverse effects. This self-limiting mechanism is likely to be applied to a number of susceptible sub-populations including insomniacs, patients with anxiety disorders or panic disorder, migraineurs in whom caffeine is a trigger, people with genetic polymorphisms that make them unusually susceptible to the adverse effects of caffeine, people allergic to caffeine, and people experiencing changes in caffeine clearance due to commencing oral contraceptives or quitting smoking.

Most potentially sensitive sub-populations identified in FSANZ's review (see SD 1) may be expected to be managed by the medical profession or by prescribing pharmacists. These include antagonistic, additive, potentiating or synergistic effects with prescription medications, and a number of specific contraindications of caffeine including familial long QT syndrome, Brugada syndrome, mitral valve prolapse, left ventricular hypertrophy, cardiomyopathy (or history of cardiomyopathy), Tetralogy of Fallot, aortic aneurysm, epilepsy being treated with phenobarbital during pregnancy, migraine being medicated with triptans, history of ocular hypertension or glaucoma, some psychiatric disorders (such as anxiety disorders and panic disorder), and adrenergic urticaria. The medical profession may also advise patients with a history of migraine to consume less than 200 mg caffeine per day and to be consistent in the time/s of consumption; prescribe long-acting pain relievers to migraineurs who consume coffee and undertake periods of fasting; and advise people at risk of Huntington's disease to limit caffeine intake to ≤ 190 mg caffeine/day.

2.1.5 Additional comments

Epidemiological evidence indicates that habitual coffee consumption is neutral to beneficial regarding the risks of hypertension, coronary heart disease, congestive heart failure, arrhythmias and stroke. Habitual coffee consumption is associated with decreased risk of type 2 diabetes, several types of cancer, hepatic fibrosis and cirrhosis, development of gallstones and kidney stones, and risk of Parkinson's disease, Alzheimer's disease, and general age-related cognitive decline. The beneficial effects of coffee may not be entirely attributable to caffeine and therefore may not be applicable to products in which pure caffeine is an ingredient, such as energy drinks or other sports supplements.

2.1.6 Conclusions

Chronic moderate consumption of caffeine at up to 400 mg/day is not associated with significant adverse effects in the general adult population. The caffeine intake of pregnant women should be limited to ≤ 200 mg caffeine/day. There is a lack of information on which to base recommendations of safe levels for breastfeeding women.

Single intakes of caffeine of up to 210 mg (approximately 3 mg/kg bw) are not generally associated with any adverse effects.

Caffeine consumption poses a risk of acute toxicity to infants and small children.

Safe levels of caffeine for children and adolescents in the range 2.5 to 3.0 mg/kg bw/day have previously been extrapolated from adults based on bodyweight. However, 3.0 mg/kg bw/day has been associated with adverse effects on emotional states in children, and above 1.4 mg/kg bw/day has been associated with sleep disturbance in children. The rate of clearance of caffeine in adolescents is comparable to that of adults, so caffeine intake up to 5.7 mg/kg bw/day is likely to be safe for this age group.

Most of the contraindications of caffeine identified in SD 1 may be expected to be managed by consumers, by the medical profession or through advice provided by pharmacists. Sub-populations at potential risk that are not managed through these avenues include users of supplements that are not accurately labelled, infants and pre-schoolers and athletes. It is evident from case histories and poison centre data that caffeine consumption poses a risk of acute poisoning to infants and small children, due to their low bodyweights. There is evidence of a lack of awareness of the hazards of caffeine, particularly in athletes and adolescents.

2.2 Dietary intake assessment

Full details of the dietary intake assessment (DIA) are in SD 2.

The objectives of the DIA were to:

- estimate the usual intakes of caffeine from foods and beverages for Australian and New Zealand population groups and determine if intakes exceed recommended maximum levels
- estimate the intakes of caffeine from sports foods and beverages, and dietary supplements for relevant Australian and New Zealand consumers
- identify the major food group contributors to caffeine intakes for Australian and New Zealand population groups.

2.2.1 Methodology and approach

Food consumption data used for the dietary intake assessment came from the 2011-12 Australian National Nutrition and Physical Activity Survey (2011-12 NNPAS) and the 2008-09 New Zealand Adult Nutrition Survey (2008 NZANS).

Caffeine concentration data were from the databases used in the 2011-12 NNPAS and 2008 NZANS. Where relevant, these data were updated to reflect more recent data from Australian and New Zealand food composition databases, food labels and product websites.

Usual intakes of caffeine from foods and beverages for all respondents were estimated using the National Cancer Institute (NCI) Method (National Cancer Institute 2021) for Australian population groups, and the “2nd day adjusted” (or within-person variability adjustment) method (Sempos et al. 1991) for New Zealand population groups. Usual caffeine intakes were calculated to better estimate the proportion of Australian and New Zealand population groups who exceed the recommended maximum levels for chronic (or habitual) intake identified in SD 1.

One day caffeine intakes for Australian and New Zealand sports food and beverage consumers, and the contribution of different food groups to the caffeine intake of all consumers, were estimated using FSANZ’s dietary modelling computer program Harvest.

An evaluation of caffeine intakes from dietary supplements for Australians was also conducted.

The Australian population groups included in the assessment were children (2-4 years, 5-8 years, 9-12 years), adolescents (13-19 years), adults (20 years and above) and women of childbearing age (16-44 years). The New Zealand population groups included in the assessment were adults (15 years and above) and women of childbearing age (16-44 years). Subpopulation groups of sports food / beverage consumers and dietary supplement consumers were also included.

2.2.2 DIA results and discussion

Caffeine was consumed by 87% of Australians and 93% of New Zealand adults on day one of the national nutrition surveys.

Mean usual intakes of caffeine across all population groups assessed were 3-172 mg/day for Australians aged 2 years and above, and 97-142 mg/day for New Zealand adults. Estimated usual intakes for the population groups assessed indicated that no or few children and adolescents, and up to 6% of adults, had a caffeine intake that exceeded the recommended maximum levels. A greater proportion of women of child-bearing age had usual caffeine intakes greater than the recommended maximum level for pregnant women, however this is likely an overestimation as there is evidence that pregnant women may reduce their caffeine intake during pregnancy.

The highest contributing food group to day one caffeine intakes was non-alcoholic beverages for all population groups assessed. Within this group, coffee, tea and soft drinks were major (>5%) contributors of caffeine for different population groups. Other major contributors to caffeine intakes for different population groups included sweet biscuits, cakes and muffins, flavoured milk and milkshakes, chocolate and chocolate-based confectionery, and sports foods and beverages.

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

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

Although caffeine concentrations were updated where possible, a limitation of this dietary intake assessment is that these data do not reflect changes in the consumption of caffeinated food and beverages over the past 10 to 12 years, for example, sports foods and beverages. From 2012/13 to 2016/17, sales of sports nutrition products (including sports related supplements) in Australia grew by 7%, with an estimated value of $495 million in 2016/17 (Office for Sport-Department of Health 2020). Changes in Australian and New Zealand food and beverage consumption patterns and caffeine intakes resulting from changes to the food supply will be reflected in future national nutrition surveys.

2.3 Social science assessment

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

The assessment drew on a rapid systematic review that FSANZ undertook to examine the available evidence on consumer behaviour, understanding, risk perceptions and information sources regarding caffeinated foods and beverages (see SD 3). The review examined 65 studies, predominantly from Australia and New Zealand, except for the sub-populations of children and pregnant/lactating women where it was necessary to draw on the international literature to supplement a small number of available studies. No studies were found that examined caffeine-sensitive individuals in either context, and there was limited data available on athletes. The review was externally peer reviewed by an independent expert. Details of the limitations associated with the review are available in SD 3.

The findings complement and extend the findings of FSANZ's DIA, particularly for the subpopulation of pregnant women, which was not able to be directly examined in the DIA. Although not all studies in the social science review utilised nationally representative samples comparable to those employed in the DIA, some provided more recent consumption information than that available in the national dietary surveys (collected in 2011-2012 and 2008-2009 in Australia and New Zealand respectively).

2.3.1 General foods

Caffeinated food and beverage products are consumed by most children (58.3% - 87%), adolescents (94.9%), pregnant women (42% - 95.3%) and the general population (99.1%). No information was available regarding the amount of caffeine being consumed by athletes. The majority of each examined subpopulation appear to be consuming caffeine within the recommended maximum daily limits (i.e. 400 mg/day for adults; 5.7 mg/kg bw/day for adolescents; 3 mg/kg bw/day for children; and 200 mg/day for pregnant/lactating women). However, there was evidence that a subset of pregnant women (typically less than 15%) and 14 - 33% of some adult sub-populations regularly exceed their respective recommended maximum daily limits of caffeine. There was little evidence that children or adolescents are regularly overconsuming caffeine.

Among the three studies that reported on overconsumption of caffeine among adult sub-populations, the lower end of the range (14%) involved a convenience sample of 317 New Zealand university students who answered a caffeinated food frequency questionnaire. The upper end of this range (33%) was found among 97 mostly female Australian nurse and midwife shift workers who answered a questionnaire that included questions on average daily consumption of coffee, tea, and cola-type drinks. The third study, which found that 17% of participants were exceeding 400 mg/day, used a non-representative convenience sample (n=2,379) of the New Zealand population that skewed both young and female subjects who answered a caffeinated food frequency questionnaire. These proportions are notably higher than the proportions found from the DIA, which is likely to be due to the smaller, non-representative sampling methods that these studies typically employed, different dietary assessment and data analysis methodologies, and/or the relative recency of the data.

In addition, one Australian study found that a small subset of adolescents (exact proportion not quantifiable, however, less than 3.4%) may be exceeding the recommended maximum daily limit of caffeine in an average 'session' of energy drink consumption. However, as the exact proportion is unquantifiable and the frequency of these sessions was not reported, it is unclear whether this is a substantial finding.

Coffee is the major contributor to exceeding the daily recommended limits of caffeine for pregnant women and the general population. In addition, two studies found that a subset of individuals from the broader population (proportion not quantifiable) are either regularly reaching or exceeding the recommended maximum daily limit of caffeine solely by consuming energy drinks. Energy drinks was also identified as the sole source of overconsumption for a small subset of adolescents (proportion not quantifiable), although it is not clear if this was occurring on a regular basis.

Consumers' motivations for consuming caffeinated food and beverages varied across different food products and sub-populations, but common themes were taste, desire for increased energy, and social considerations. It is unclear whether consumers are aware of the recommended maximum daily limits, or the health risks associated with overconsumption of caffeine, as no studies directly examined this. Although pregnant women typically sought information to assist with dietary changes, and had a tendency to reduce caffeine intake, it is not clear they were aware of, or had received advice consistent with, the 200 mg/day recommended maximum limit. In addition, there is evidence to suggest that perceived negative side effects from consuming caffeinated food and beverage products do not always lead consumers to reduce their caffeine intake: in one study, coffee and energy drinks were still regularly consumed by New Zealand university students despite experiencing adverse symptoms, including being unable to sleep, a fast or uneven heartbeat and an upset stomach.

There was no information available on whether consumers were aware of the caffeine content associated with foods that naturally contain caffeine such as tea and coffee. However, there was evidence that consumers may not always be aware that caffeine has been added to certain beverages. Specifically, two studies suggested that some younger adolescents are unaware that energy drinks contain caffeine, and one study found that some consumers from the broader population are unaware that caffeinated ready-to-drink alcoholic beverages contain caffeine. When asked, consumers expressed a desire for additional information about the caffeine content of energy drinks, in particular the daily limits, specific health risks and recommended age limits. However, these studies did not examine the effect of these potential labelling changes on consumers' consumption behaviours, and this was beyond the scope of the current literature review.

There was insufficient information available on consumers' awareness of either the daily maximum recommended limits or the caffeine content of foods that naturally contain caffeine (e.g. tea and coffee) to make an assessment about the impact of consumer knowledge on caffeine consumption behaviour for these products. Although there was evidence that consumers do not always self-regulate their caffeine intake even when experiencing perceived negative side effects, it is unclear whether consumers are aware of or consider these side effects to be a substantial risk to their health.

2.3.2 Social science assessment of sports foods

The social science literature found that up to 19.5% of adults, including those both active and sedentary, may consume sports foods. Sports foods were not found to be a major contributor to daily caffeine intake in children, adolescents or a sample of university students. No studies directly examined the contribution of sports foods products to total caffeine intake in athletes, pregnant women or the general population.

There was some evidence that caffeinated sports foods products might pose a risk among athletes and the general population. However, this evidence was limited by a lack of direct examination of the contribution that sports foods make to daily caffeine intake, and category definition issues in which the 'caffeine/sports supplements' measured included but also extended beyond the definition of FSSFs within the Code.

One study found that a subset of individuals from the general population (proportion not quantifiable) may be exceeding the daily safe limit of caffeine solely by consuming caffeine tablets, medications and/or sports supplements. It is not possible to determine which of these products was the major contributor to exceeding the daily recommended limit of caffeine as they were combined into one category.

The available evidence also suggests that some consumers among athletes, military personnel and the general population may consume multiple sports foods products, although it is unclear if the products in question contained caffeine. Five quantitative studies reported that athletes/military personnel consume multiple sports foods products, however, it is unclear whether these are consumed within the same day (i.e. stacking behaviour). One qualitative study found that both physically active and sedentary consumers from the general population use multiple types of sports food products within the same day.

2.3.3 Social science conclusions

2.3.3.1 Children

There is very little evidence that Australian or New Zealand children are regularly consuming caffeine in excess of 3 mg/kg bw/day.

2.3.3.2 Adolescents

Although there was some evidence that younger adolescents may be unaware of the caffeine content of energy drinks, there is little substantial evidence that adolescents are regularly consuming caffeine in excess of 5.7 mg/kg bw/day.

2.3.3.3 Pregnant/Lactating Women

There is evidence that a substantial subset of consumers among pregnant women (typically less than 15%) are regularly exceeding the recommended maximum daily limit of caffeine from the foods that are currently available in the Australian/New Zealand food supply. Coffee was the major contributor to overconsumption. While the majority of pregnant women are consuming within the recommended limits, it is not clear whether they were aware of, or had received advice consistent with, the 200 mg/day caffeine limit.

2.3.3.4 Adults

The social science literature review found that there is some evidence that the prevalence of caffeine intake in excess of 400 mg/day may differ across different sub-populations of the general adult population. Non-nationally representative food frequency questionnaire studies found that 14% of university students, 17% of a relatively young and female subsection of the general population and 33% of nurse and midwife shift workers usually consumed caffeine in excess of 400 mg/day.

Coffee was the major contributor to overconsumption. It is unclear why adults are overconsuming. There was insufficient information available to make an assessment about the impact of consumer knowledge on caffeine consumption behaviour.

2.3.3.5 Athletes

There was no information available regarding the amount of caffeine being consumed by athletes.

2.3.3.6 Sports Foods

From the social science evidence, it is unclear whether sports foods are a major contributor to overconsumption of caffeine in athletes, pregnant women and the general population. However there is evidence that athletes, military personnel and the general population may be consuming multiple types of sports foods products within the same day (i.e. stacking). Although it is not clear that these products contained caffeine, this finding provides insight into how consumers use sports foods more broadly and suggests that consumers may be at risk of inadvertently exceeding the recommended maximum daily limit of caffeine due to stacking behaviour if they are unaware of the amount of caffeine in sports foods products. There was no information available regarding consumer awareness of the amounts of caffeine in sports foods, nor understanding of the recommended daily maximum limit of caffeine.

2.4 Discussion

2.4.1 Risks to children from caffeinated foods

Infants and pre-schoolers are at risk of acute life-threatening caffeine poisoning due to their low bodyweights. Although their exposure to caffeine may be rare, the outcome is likely to be severe or catastrophic. Internationally, infants and pre-schoolers are a subpopulation at high risk, and available data from poisons centres in Australia and New Zealand indicate that these groups are over-represented among cases of accidental caffeine consumptions and acute caffeine toxicosis.

The DIA found that in Australia, no children aged between 2-4 years and 5-8 years, and less than 1% of children aged 9-12 years, had a usual caffeine intake greater than 3 mg/kg bw/day. The social science assessment also found that children do not usually exceed the 3 mg/kg bw/day of caffeine. Safe levels of caffeine for children in the range 2.5 to 3.0 mg/kg bw/day have previously been extrapolated from adults based on bodyweight. However, 3.0 mg/kg bw/day has been associated with adverse effects in children, and above 1.4 mg/kg bw/day has been associated with sleep disturbance in children.

2.4.2 Risks to adolescents from caffeinated foods

Caffeine clearance in adolescents is likely to be at least that of adults, so the recommended level for adults (i.e. 5.7 mg/kg bw/day) is also applicable to adolescents. Internationally, it has been reported that adolescents may lack awareness of the adverse effects of caffeine. In Australia and New Zealand, there is some evidence that younger adolescents may be unaware of the caffeine content of energy drinks, but the DIA found that less than 1% of Australian adolescents had a usual intake greater than 5.7 mg/kg bw/day. This was consistent with the social science assessment, which found no substantial evidence that adolescents are regularly consuming caffeine in excess of 5.7 mg/kg bw/day.

2.4.3 Risks to adults from caffeinated foods

Chronic moderate consumption of caffeine at up to 400 mg/day (5.7 mg/kg bw/day based on a 70 kg bodyweight) is not associated with significant adverse effects in the general adult population. Consumers generally learn to regulate their intake to achieve the beneficial effects of caffeine while avoiding serious adverse effects. FSANZ notes that habitual consumption of coffee is associated with numerous beneficial effects, although it is not clear whether these are all attributable to caffeine. Several sensitive sub-populations were identified in the safety assessment (SD 1) but most of these sub-populations would be managed by medical professionals or through advice provided by pharmacists.
Using data from the most recent National Nutrition Surveys, the DIA found that 6% or fewer Australian and New Zealand adults had usual (or longer term) intakes greater than 400 mg/day.

The social science literature review found that there is some evidence that the prevalence of caffeine intake in excess of 400 mg/day may differ across different sub-populations of the general adult population. Non-nationally representative food frequency questionnaire studies found that 14% of university students, 17% of a relatively young and female subsection of the general population and 33% of nurse and midwife shift workers usually consumed caffeine in excess of 400 mg/day.

In all studies from the social science literature review, coffee was found to be the major contributor to overconsumption. Although there is evidence that some consumers may exceed the recommended maximum of 400 mg/day, there is a lack of evidence that adults frequently develop serious signs of acute caffeine poisoning such as arrhythmia or seizures.

2.4.4 Risks to pregnant and lactating women from caffeinated foods

There are positive associations between caffeine consumption and miscarriage, stillbirth, preterm delivery, low birthweight and small for gestational age (SGA) infants. The associations are generally modest within the range of usual dietary intake, and the results suggest that a maximum of 200 mg caffeine/day is acceptable for pregnant women.

There is evidence that a significant subset of pregnant women (typically less than 15%) are regularly exceeding the recommended maximum daily limit of caffeine (200 mg/day) from the foods that are currently available in the Australian/New Zealand food supply, principally through consumption of coffee. While most pregnant women are consuming less than 200 mg/day, it is not clear whether they are aware of, or have received advice concerning, this limit.

There is very little information on the effects on breastfeeding infants from maternal caffeine exposure. FSANZ notes that caffeine is used at very high doses to prevent apnoea of prematurity in infants born preterm, with no long-term adverse physical or psychological

sequelae.

2.4.5 Risks to athletes and users of sports foods

Internationally, studies indicate that athletes are at relatively increased risk of acute caffeine poisoning. There are no data on the use of caffeine by athletes in Australia or New Zealand. A maximum level of 400 mg/day is considered safe for athletes and users of sports food. Consumers may be at risk of inadvertently exceeding this recommended limit if they are unaware of the amount of caffeine in sports foods products.

2.5 The effect of caffeine on aerobic exercise performance in the general population

2.5.1 Methodology and results

FSANZ assessed evidence from human trials investigating the impact of caffeine intake on time trial performance in sports including cycling, running, rowing and swimming. Forty publications representing 39 studies and 42 pairwise comparisons were included. Eligible studies were mostly crossover trials with treatment order (caffeine or placebo) randomised, although most did not state a randomisation method.

Mean effect estimates from meta-analyses indicate that caffeine intake is associated with an observed faster time trial performance when compared to placebo. Using a standard scale of effect size, a small magnitude of effect was demonstrated by a meta-analysis of all 42 pairwise comparisons, using a pooled 674 participants, and a caffeine dose range of 1.25–9 mg/kg bw.

FSANZ did not find a relationship between caffeine dose and effect size. Separate meta-analyses of time trial performance with the following caffeine dose ranges/doses gave similar effect sizes: 1.25–3 mg/kg bw; 4–6 mg/kg bw; 5 mg/kg bw; and 6 mg/kg bw. A meta-analysis was not conducted for caffeine doses above 6 mg/kg bw as only two studies were available.

The level of certainty of the body of evidence is low. This means that our confidence in the effect estimate is limited; the true effect may be markedly different from the estimated effect. FSANZ's certainty in the evidence is reduced to 'low' due to risk of bias and indirectness. Most studies did not state a randomisation method and some studies were not randomised. Most of the study participants were young adult males who were trained athletes with a high aerobic capacity. FSANZ have a low level of certainty that the effect size from analysis of the current data will apply to females, other age groups (children, adolescents, and older adults), untrained or unfit people, or for sports where performance is not correlated with aerobic exercise capacity.

The level of certainty of a body of evidence can be categorised into one of four categories: very low, low, moderate, or high. The certainty of a body of evidence indicates how confident we are that the estimated effect size, from our evidence synthesis, represents the true effect. Multiple systematic reviews and meta-analyses of caffeine intake on aerobic endurance have been published which include assessments of evidence certainty. An umbrella review by Grgic et al. (2020) identified five systematic reviews (Doherty & Smith 2004, Conger et al. 2011, Ribeiro et al. 2017, Southward et al. 2018, and Shen et al. 2019) with a total of nine meta-analyses, to examine the effects of caffeine on aerobic endurance in healthy individuals. The level of certainty of the body of evidence included in each meta-analysis was categorised by Grgic et al. (2020) as low for four meta-analyses, very low for two, and moderate for three. In a separate publication, meta-analytical evidence to evaluate the effect

of caffeine on aerobic endurance performance in soccer players was graded by a different pair of reviewers. They graded the body of evidence as having a very low (four meta-analyses) to low (one) level of certainty (Ferreira et al. 2021). The level of certainty in the evidence that FSANZ assessed is therefore consistent with that of 14 published meta-analyses.

FSANZ concludes with a low level of certainty that caffeine has a small beneficial effect, that is, a faster time trial performance after caffeine intake when compared to placebo. The lowest and highest dose level at which a small beneficial effect is observed lies within the range 1.25–3 mg/kg bw and at 6 mg/kg bw, respectively.

3 Risk management

3.1 Options

FSANZ undertook an analysis of various risk management options as part of this proposal. The draft regulatory options currently being considered are outlined below.

Option 1 – Status quo approach

The *status quo* must be considered by FSANZ in any proposal to change the Code. Under this option, the current provisions for caffeine in the Code would remain unchanged. This would mean that the P1054 variation remains in place. This option does not introduce any new express permissions or prohibitions for adding caffeine to food.

This option does not include any additional risk management measures and would not address any risks identified during the risk assessment, such as the risk to pregnant women (more specifically, the foetus) or infants and pre-schoolers. As outlined in Sections 2.1.3 and 2.1.4.4, infants and pre-schoolers are at risk of acute toxicity due to their low bodyweight. This is confirmed by data from poison centres which indicate that infants and pre-schoolers are over-represented among hospitalizations and fatalities due to acute caffeine poisoning.

Additionally, single intakes of caffeine of over 210 mg have been associated with adverse health effects in the general population. These effects include increase in blood pressure, plasma catecholamines and anxiety at lower intakes, leading to more serious effects such as tachycardia, ventricular arrhythmia or seizures at acute consumption levels (see Table 2 in Section 2.1.3). Subject to their serving size and use (dilution for example) some foods meeting the 1 or 5% limits developed during P1054 specifically to address highly concentrated caffeinated products, could potentially still contain well over 210 mg caffeine per serving.

This option does not reflect that caffeine is a substance that has maximum safe daily intake recommendations, that vary depending on age and population group.

The status quo is therefore not the preferred option.

Option 2 – Status quo combined with non-regulatory approach

This would leverage consumer education materials on the risks of pure and highly concentrated caffeine products already on the FSANZ website. Key messages that explain the specific risks identified for each at-risk sub-population, would be incorporated into any resources developed.

The safety assessment also concluded that there is a lack of understanding of the hazards of caffeine by some population groups, which may include parents or caregivers. Therefore education materials would provide information for parents and caregivers of infants and pre-schoolers.

This option would not involve amending the Code.

FSANZ considers that this option alone would not be sufficient to address the identified risks and is therefore not the preferred option.

Option 3 – Hybrid mix of regulatory and non-regulatory approaches

The proposed regulatory measures are:

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

This hybrid approach includes the non-regulatory options outlined in option 2 above. This is FSANZ's preferred option.

The setting of a maximum one-day quantity in FSSF allows for an amount of caffeine that has a demonstrated ergogenic benefit informed by FSANZ's assessment of caffeine and sports performance and helps to ensure safety for consumers of these products in the context of their normal daily caffeine consumption from all sources. The maximum one-day quantity will also provide certainty to manufacturers of FSSF and jurisdictional enforcement agencies, whilst still allowing innovation in these types of products. It will also render non-compliant, FSSF which contain higher than the proposed permitted one-day quantity.

The express prohibition on the addition of caffeine to foods for retail sale unless explicitly permitted would reduce the likelihood of caffeine becoming more widespread in the general food supply and therefore ensuring the safety of at risk consumers. Under this option, the issues outlined under option 1 above would be addressed.

Addition of caffeine to foods for retail sale would only be permitted where specified. This would not affect the ability to sell foods that contain caffeine by natural occurrence, for example coffee, tea and chocolate unless the novel foods provisions apply as mentioned in section 1.5.2.5 above. The current regulation of caffeine in cola-type drinks and FCBs would remain unchanged.

The express prohibition on the addition of caffeine to foods for retail sale unless explicitly permitted means that the P1054 variation, relating to highly concentrated caffeinated products, would be no longer required and would be omitted from the Code.

3.2 Regulatory measures

FSANZ has had regard to the requirements of the FSANZ Act (see section 3.5) in developing the proposed regulatory measures. In doing this, FSANZ has considered the evidence of any public health and safety risk associated with caffeine consumption.

3.2.1 Permission for caffeine in FSSF

Standard 2.9.4 – Formulated Supplementary Sports Food regulates the composition and labelling of foods specially formulated to assist sports people in achieving specific nutritional or performance goals. At present, Standard 2.9.4 does not explicitly permit the addition of caffeine to FSSF.

FSANZ has considered the evidence of any public health and safety risk associated with caffeine consumption, as well as caffeine's usefulness for consumers of FSSF. FSANZ has also considered the *Policy Guideline on the Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods*, which sets out specific policy principles including that the composition of special purpose food should be consistent with the intended purpose. Finally, FSANZ has considered the impact that regulation may have on FSSF manufacturers and distributors in Australia and New Zealand, and the international regulatory environment in proposing the approach outlined in the following sections.

3.2.1.1 Regulatory approach in Standard 2.9.4

The following definition in the Code describes the intended purpose and population for consumption of FSSF:

formulated supplementary sports food means a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals.

Schedule 29—Special Purpose Foods specifies the maximum amount of certain substances that can be added to a 'one-day quantity' of a FSSF. A 'one day quantity' is defined as follows:

one-day quantity, in relation to a formulated supplementary sports food, means the amount of that food which is to be consumed in one day in accordance with directions specified in the label.

The associated labelling requirements for FSSF are outlined in Section 3.4.2 below.

3.2.1.2 The effect of caffeine on aerobic exercise performance in the general population

As outlined in Section 2.5.1 above, FSANZ found that caffeine intake in exercising and sports people at ranges between 1.25 mg/kg bw and 6 mg/kg bw provided a beneficial ergogenic effect (measured by faster completion of time trials testing aerobic exercise performance, see SD 4). An improvement in exercise performance from caffeine consumption is aligned with the Code's defined purpose of FSSF (see above) and reflects the primary purpose of consumption in supporting physical performance goals.

3.2.1.3 Sports food consumption in Australia and New Zealand

Research from Australia and New Zealand suggests that sports foods consumption is also no longer limited to athletes, thus proposed regulatory measures under Standard 2.9.4 must take into account the safety and suitability of caffeine consumption by the general population. In considering any permission to add caffeine to FSSF, the total amounts of caffeine consumed across the population's typical diet should be taken into account. While FSANZ notes that much of the general population appear to consume caffeine within the recommended maximum daily limit (<400 mg/day for adults, adolescents and athletes), there is a notable subset (around 14-33%) exceeding that limit on a regular basis (see Section 2.3.1), some of whom may be consumers of sports foods. This was further supported by the dietary intake assessment (SD 2, Section 3.1), which showed that while the mean usual intakes of caffeine across all population groups were within the recommended daily maximum limit (42-172 mg/day for Australians aged from 13 years and above and 124-142 mg/day for New Zealand respondents aged 15 years and above), up to 6% of adults had a caffeine intake that exceeded the maximum daily limit. Thus a permission to add caffeine to FSSF must protect the subset of the population who may be consuming in excess of the maximum daily limit.

FSANZ's safety assessment at SD 1 found that users of sports foods may also fail to appreciate the risks associated with excessive caffeine consumption. Jagim et al (2019) found that while most users followed the package instructions regarding serving size, 14% reported they consume two or more serving sizes at a time and 18% reported using pre-workout sports products more than once a day (pre-workout sports foods most commonly contain caffeine). More than one-third of respondents to the electronic survey (34.9%) also reported using other sources of caffeine at the same time. More than half (54%) of respondents reported adverse effects that they attributed to the use of pre-workout supplements.

FSSF are easily and widely available to the community via supermarkets and specialty stores, petrol stations, gyms and on-line purchase, and are promoted for a variety of purposes. Also of concern, many products recommend 'stacking' with other products (which promotes consumption of multiple products in one day) or have recommendations on their labels which promote taking a 'double serve' prior to an exercise session. These practices further increase the potential for risk of excess caffeine consumption.

3.2.1.4 Current advice on the use of caffeine in elite sports

FSANZ must also have regard to consistency between domestic and international food standards when developing or varying a food standard. Alignment with international regulations has been outlined in Attachment 2 of this document. Due to the defined purpose of FSSF (i.e. benefit to sports performance), it is prudent for FSANZ to also consider the regulation of caffeine by international sporting bodies. As such, FSANZ had regard for the following recommendations on the use of caffeine in elite sports:

- The EFSA Panel on Dietetic Products, Nutrition and Allergies released a scientific opinion in 2015 on the safety of caffeine which concluded that single intakes of caffeine up to 200 mg (about 3 mg/kg bw for a 70 kg adult) do not give rise to safety concerns.
- The International Olympic Committee (IOC) consensus statement indicates maximal benefits are achieved with intakes of between 3-6 mg/kg/bw and unwanted outcomes (adverse effects) are more common at 9 mg/kg/bw or more.
- The World Anti-Doping Agency (WADA) has included caffeine on its monitoring list, acknowledging its increased use in sport. The Monitoring Program includes substances which are not on the Prohibited List, but that WADA wishes to monitor in order to detect patterns of misuse in sport.
- The United State Anti-Doping Agency (USADA) aligns with the above WADA recommendations and only imposes limitations on caffeine intake at National Collegiate Athletic Association (NCAA) sanctioned events (noting it bans caffeine intake from guarana only).
- The Australian Institute of Sport (AIS) Supplement Framework classifies caffeine as a Group A substance, considering it to have strong scientific evidence that it can support or improve sports performance in some sport scenarios at (e.g. 2-3 mg/kg (~200 mg)) before or during exercise.

3.2.1.5 Public health considerations of caffeine in sports foods

FSANZ's safety assessment at SD 1 concluded that chronic, moderate consumption of caffeine in foods in adults is safe at up to 400 mg/day. However, it also concluded that acute intakes of caffeine over 210 mg/serve (approximately 3 mg/kg bw) is associated with adverse health effects including increased blood pressure, plasma catecholamines and anxiety. FSANZ notes that the majority of caffeine consumption occurred through non-alcoholic beverage consumption and not through sports foods. Given the discussion above in Section 3.2.1.3 however, the risk to public health and safety lies predominantly with the portion of the population who exceed (or come close to exceeding) the recommended maximum intakes of caffeine. It follows that this risk is increased for those who regularly consume FSSF that also contain caffeine.

3.2.1.6 Proposed maximum level for caffeine in FSSF

FSANZ has considered the following key points in proposing a maximum level of caffeine in FSSF:

- A small subset of the population is consuming excessive caffeine (or close to excessive), some of whom may deliberately seek out higher levels of caffeine in FSSF for its ergogenic effects.
- There is a demonstrated ergogenic effect at levels that in acute intakes do not exceed safe levels (approximately 200 mg).
- As stated in section 1.5.4 above, some sports products containing caffeine will be regulated under other legislation, for example under the TG Act in Australia.
- Caffeine is permitted for use in elite sport internationally by peak sporting bodies at intakes from 3-6 mg/kg bw (approximately 200-400 mg/serve).

In considering the safety and intended purpose of adding caffeine to FSSF, FSANZ also considered the requirements within the existing regulatory arrangements in Standard 2.9.4, including labelling to advise against the use of these products by children under 15 years of age and pregnant women. FSANZ also notes that an increasing number of sports products already available on the Australian and New Zealand market that are not regulated by the TGA sometimes contain levels over 210 mg/serve. With regards to FSANZ's safety assessment which concluded that acute intakes of caffeine over 210 mg/serve are associated with adverse health effects, this presents an immediate risk to public health.

FSANZ proposes to explicitly permit in a FSSF, total caffeine up to a maximum of 200 mg in a one-day quantity, in conjunction with appropriate labelling requirements (see Section 3.2.1.9). This would mean that a consumer using a FSSF as directed on the label may consume a maximum of 200 mg of caffeine in one day from a single serve or through multiple serves of that FSSF, subject to the amount of caffeine in a serving. In conjunction with the mean caffeine intake from all other food sources, total intake is not expected to exceed the recommended maximum daily limit of 400 mg/day for consumers who are using FSSF in accordance with the directions on the label to support their increased dietary requirements for exercise.

This approach is based on the safety data for both chronic and acute usage, as well as consideration of the demonstrated ergogenic benefit of caffeine and existing permissions in international regulations and set by peak sporting bodies. FSANZ considers the proposed level to be both appropriate for managing the risk of excessive intake in consumers as well as providing some benefit to sporting performance.

The setting of a maximum one-day quantity for caffeine added to a FSSF is consistent with

the permissions for adding substances to FSSF already contained in Standard 2.9.4. This approach recognises that FSSF are special purpose foods, and in the case of FSSF, are '*a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals*.' The maximum one-day quantity will also provide certainty to manufacturers of FSSF and jurisdictional enforcement agencies.

It is proposed that caffeine is permitted to be added to FSSF in the same way that the caffeine permission in FCBs operates. This means that the permission to add caffeine to FSSF is not as a food additive (flavouring) but is for a physiological purpose.

3.2.1.7 Minimum level for caffeine in FSSF

FSANZ is not proposing to require a minimum amount of caffeine in FSSF that contain caffeine. FSANZ considers that there can be inter-individual differences in caffeine metabolism and sensitivity, and setting a minimum effective amount is not appropriate. This is consistent with overseas permissions, which also do not specify a minimum amount of caffeine to be included in sports foods.

3.2.1.8 Labelling of formulated supplementary sports foods containing caffeine

FSANZ has considered possible requirements for the labelling of FSSF containing added caffeine as a result of the proposed approach to specifically permit caffeine in FSSF up to a maximum of 200 mg per one-day quantity, as detailed in the following sections.

3.2.1.8.1 Advisory statement 'contains caffeine'

FSANZ proposes to require an advisory statement using wording to the effect of 'contains caffeine' on the label of all FSSF containing caffeine, irrespective of the source or amount. For FSSF not required to bear a label under Standard 1.2.1, FSANZ is proposing to require the advisory statement to be provided either in connection with the sale of the food or upon request, for example, on a sign or verbally if asked. This is consistent with the current approach for the provision of advisory statements in Standard 1.2.1.

The actual wording of the advisory statement on the label would not be prescribed.

This requirement would be consistent with the advisory statement currently required on other foods with specific permission to contain added caffeine, such as cola-type beverages and FCBs. Noting the risks associated with consumption of caffeine for different population groups (refer to Sections 2.1.3 and 2.1.4 above), it is proposed that consumers are alerted to the presence of caffeine via the advisory statement, irrespective of its source or the amount present, given they may not expect FSSF to contain caffeine. This is unlike tea or coffee for example, which are not required to be labelled with the advisory statement given consumers are more likely to be aware these products contain caffeine.

3.2.1.8.2 Declaration of amount of caffeine and one-day quantity

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

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

As outlined in Section 3.2.1.7 above, the 'one-day quantity' must not exceed 200 mg. The FSSF Standard currently includes requirements to label with directions stating the recommended amount and frequency of consumption of the food and a statement of recommended consumption in one day (section 2.9.4—4). Therefore, these instructions should not direct consumers to consume more than 200 mg per day of caffeine from the FSSF. No amendments to these existing labelling requirements are proposed under this proposal. There are currently no requirements for these directions to be provided for FSSF not required to bear a label. FSANZ is proposing to maintain this approach under this proposal but to consider it more broadly for all FSSF under Proposal P1010.

FSANZ considers the existing labelling requirements would require the provision of appropriate information to consumers about caffeine and enable enforcement of the proposed one-day quantity requirement, when the proposed NIP entry is read in conjunction with the directions for use. Additionally, the requirement to declare caffeine in the NIP will assist with preventing consumers being misled from FSSF containing minimal or ineffective amounts of caffeine with respect to sports performance but labelled as containing caffeine (in accordance with the proposed advisory statement), as they will be informed about the quantity present.

FSANZ considers it is appropriate to require the declaration in the NIP as this is consistent with the approach to declare biologically active substances in the panel if a nutrition content or health claim is made. It also allows for the prescribed format of the NIP to apply to the caffeine declaration for consistency across FSSF containing caffeine. It is however noted that this approach differs to the approach for FCBs whereby caffeine is not to be in the NIP but can be below it.

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

3.2.1.8.3 Other advisory and warning statements

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

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

FSANZ is not proposing to require a warning or advisory statement for FSSF containing added caffeine specifically for lactating women and individuals sensitive to caffeine. For lactating women, as noted in the risk assessment (Section 2.4.4 above) there is very little information on the effects of maternal caffeine exposure via breastmilk on infants. The proposed one-day quantity will limit exposure to caffeine in infants via breastmilk from consumption of FSSF containing caffeine by lactating women. For both lactating women and individuals sensitive to caffeine, FSANZ considers the proposed labelling information about the presence and amount of caffeine outlined in the above sections and existing

recommendations, advice[2] and likely knowledge of these population groups about caffeine consumption would be sufficient to manage risks to this population group if any.

3.2.1.8.4 Nutrition content claims

Nutrition content claims about FSSF are regulated by Standard 1.2.7 and Standard 2.9.4.

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

FSANZ has not identified any reason to amend the current provisions relating to nutrition content claims about caffeine as a result of the proposed specific permission to add caffeine to FSSF.

3.2.1.8.5 Health claims

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

Division 3 of Standard 2.9.4 permits products that meet one of three types of compositional specifications (high carbohydrate supplement, protein energy supplement, or energy supplement) to be labelled with claims about their use in association with exercise. For example, all three products may be labelled with claims to the effect that the product is useful before, during or after sustained strenuous exercise; an energy supplement may include claims to the effect that it may assist in supplementing the diet with an energy source as may be required during training.

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

The regulation of health claims for FSSF is being reviewed by FSANZ under P1010.

[2] For example, the following resources provide advice and information about caffeine intake when lactating: Caffeine and breastfeeding | Australian Breastfeeding Association, Caffeine and breastfeeding - BabyCenter Australia, The Australian Dietary Guidelines | Australian Government Department of Health and Aged Care, Eating for Healthy Breastfeeding Women/Ngā Kai Totika mā te Ūkaipō | HealthEd, Caffeine (foodstandards.gov.au)

3.2.2 Prohibition of caffeine in other foods

The risk assessment (see section 2.1) identified that the consumption of caffeine, either from chronic (habitual) intake or through an acute (single) dose can have significant health impacts. In particular, that:

- there is a risk to the health of the general population from consumption of caffeine in excess of either 400 mg per day, or over 210 mg in an acute (single) dose
- levels of 1.4 mg and 3 mg per kg of body weight per day has been associated with sleep disturbance and adverse effects respectively in children
- infants and pre-schoolers are at risk of life threatening caffeine poisoning from acute exposure due to their low bodyweights. Data from poison centres in Australia and New Zealand indicate that infants and toddlers are over-represented among calls related to acute caffeine exposure
- although there is evidence that pregnant women may reduce their caffeine intake during pregnancy, findings of a systematic review show positive associations between caffeine consumption and miscarriage, stillbirth, preterm delivery, low birthweight and small for gestational age infants.

The Code does not currently expressly prohibit the addition of caffeine to food for purposes other than for use as a food additive, or a processing aid, novel food or a nutritive substance. Currently only cola-type drinks and FCBs have express permission for the addition of caffeine.

The risks of exceeding the recommended maximum limits of caffeine for the various populations specified above may increase, should its addition to food become more widespread. FSANZ considers these risks and the potential addition of caffeine to foods without specific regulation sufficient to place an explicit prohibition on the addition of caffeine to all foods for retail sale unless expressly permitted. Under this approach, permission to add caffeine would be considered on a case-by-case basis. Should food businesses wish to add caffeine to other foods, an application could be made to FSANZ to amend the Code.

As stated in Section 1.5.2 above, caffeine that is in a compliant food by natural occurrence would not be impacted by this approach. This proposed approach also has no impact on the current ability under the Code to add compliant caffeine-containing foods to other foods, for example adding coffee or chocolate to a cake or confectionery.

The preferred option also supports the specific policy principles on the addition of caffeine to foods, which require FSANZ to specifically consider the risk to vulnerable population groups, consider caffeine from all sources and be informed by emerging evidence.

Urgent Proposal P1054 was prepared to prohibit the retail sale of pure and highly concentrated caffeine products. Such products may be gels, powders or similar products, usually designed for consumption in a small serving size or after dilution or reconstitution. That proposal was developed due to the unacceptably high risk for consumers from those particular products and a need to act quickly to protect public health and safety.

The proposed approach to expressly prohibit the addition of caffeine to foods, apart from the express permissions in cola-type drinks and FCBs and as proposed for FSSF, would apply to the foods that were considered to pose a risk under P1054 i.e. pure and highly concentrated

caffeinated products. This means that the P1054 variation[3] would no longer be required under the preferred option and would therefore be omitted from the Code.

3.3 Questions for submitters

FSANZ invites stakeholders to provide comment on the proposed options outlined in this paper. To help facilitate this feedback, FSANZ has also proposed a series of questions for submitters. Responses will inform a Consultation Regulatory Impact Statement (should one be required) and/or cost/benefit analysis in accordance with the FSANZ Act. Questions for consideration follow.

3.3.1 Questions for all submitters

1. Do you consider there are risks to consumers from caffeine in the current market environment, under the current regulations? Please provide any evidence or relevant examples in detail to assist FSANZ in its assessment.

2. Do you have any thoughts on FSANZ's preferred option that if caffeine is prohibited to be added to all foods apart from cola-type drinks, FCBs and FSSF, that a pre-market assessment is then required to add caffeine to any other food? If not, are there other approaches that would better address the problem?

3. Do you foresee any compliance or enforcement issues with the preferred approach of expressly permitting total caffeine in FSSF at a maximum one-day quantity of 200 mg, whilst expressly prohibiting the addition of caffeine to all foods apart from cola-type drinks and FCBs?

4. Are there other supporting measures that FSANZ should consider, whether regulatory or non-regulatory?

5. Can you share any further knowledge of current research about?
   a. the health effects of caffeine,
   b. global developments in caffeinated food products, or
   c. regulatory approaches being taken in comparable markets?

3.3.2 Questions specifically for the food industry

6. In the medium term, does your company have any plans to expand the number of SKUs that contain caffeine? What would be the nature of those SKUs?

7. Do the current regulations around caffeine, in particular where cola-type drinks and FCBs are concerned, allow for your future product development needs? If not, please explain why not and what regulation you think would be more suitable?

8. Beyond the mandated labelling imposed by the Code, is there any current or planned industry led mitigation measures to reduce consumers' exposure to caffeine?

9. Will your company be prepared to help develop non-regulatory measures to monitor and manage the number of food products that contain caffeine?

[3] The prohibition of the retail sale of foods in which total caffeine is present in a concentration of 1% or more if the food is a liquid food, or 5% or more if the food is a solid or semi-solid food.

10. For product developers considering the addition of plant or other extracts containing caffeine, do you consider these would meet the definition of a novel food and therefore require a pre-market safety assessment?

3.4 Risk communication

3.4.1 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.

Consultation with interested parties will include the statutory consultation processes specified in the FSANZ Act, including a second call for submissions.

The release of this first call for submissions will be supported by a media release, updated website information and notification via Food Standards News and social media channels.

3.4.2 World Trade Organization

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

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

This issue will be fully considered at the next stage of the assessment and, if necessary, notification will be made in accordance with Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade Agreement. This will enable other WTO members to comment on any proposed amendments.

3.5 FSANZ Act assessment requirements

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

3.5.1 Section 59 of the FSANZ Act considerations

3.5.1.1 Consideration of costs and benefits

FSANZ has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 59(2)(a)).

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo.

The Office of Best Practice Regulation (OBPR) has not yet made a decision on the need to undertake a formal Regulation Impact Statement (RIS) in relation to the regulatory change proposed. Information collected as part of this CFS will help to inform this decision when FSANZ seeks their assessment.

3.5.1.2 Costs and benefits of Option 1 - Status quo approach

The *status quo* must be considered by FSANZ in any proposal to change the Code. Under this option, the current provisions for caffeine in the Code would remain unchanged. This would mean that the P1054 variation remains in place and that there is no specific permission to add caffeine to FSSF.

This option would not address any risks to health and safety identified during the risk assessment.

This option would also not impose any costs on industry.

3.5.1.3 Costs and benefits of Option 2 - Status quo combined with non-regulatory approach

Under this option FSANZ would update its educational material on the risks of excessive exposure to caffeine in food. A particular emphasis would be put on those sub-populations deemed to be at a greater risk, such as pregnant women, infants and pre-schoolers.

Consumers will benefit from reduced risk of poor health outcomes, and government will benefit from this as a result of reduced health expenditure. The magnitude of the benefits will be dependent on:

- the extent of the education (how many it reaches) and
- the effectiveness of the education in creating behaviour change.

Industry will not be impacted by this option.

3.5.1.4 Costs and benefits of Option 3 - regulatory approach

The following impacts have been identified for industry, the community and government for the regulatory option considered. FSANZ is in the relatively early stages of this work and therefore is making a number of assumptions. Feedback is sought from stakeholders on the impacts identified. Questions have also been included that will assist in better understanding the impacts. Data that helps quantify the impacts is also welcomed.

Responses to this CFS will be used to develop a fuller assessment of the impacts of the proposed regulatory options which may extend beyond a qualitative assessment to a quantitative assessment if sufficient information and data is available.
Option 3 would:

- For FSSF:
  - Expressly permit caffeine to be added
  - Set a maximum one-day quantity of 200 mg
  - Require an advisory statement on the label that the product contains caffeine
  - Require caffeine content to be declared on the NIP

- For other foods:
  - Expressly prohibit the addition of caffeine in foods for retail sale, except where specifically permitted.

- Remove the current prohibition of the retail sale of a food in which caffeine is present in a concentration of:
  - 1% or more of the food if that food is a liquid
  - 5% or more of the food if that food is a solid or semi-solid food.

As stated in Section 1.5.2, this proposal has no impact on the sale of coffee and tea and chocolate that naturally contain caffeine, or the mixing of these foods with other foods.

Impacts on industry – sports foods

Manufacturers, wholesalers and retailers of FSSF will be impacted where existing products (or products in development) exceed the proposed maximum one-day quantity for caffeine.

These businesses would need to:

- withdraw the product from sale, or
- reformulate the product to meet the requirements (for example by reducing or removing added caffeine), or
- re-label the product to re-set serving sizes and directions for use to ensure the caffeine content is within the one-day quantity.

Each pathway to achieve compliance will result in a cost to affected businesses.

Label surveys were conducted in 2018 (Desbrow et al 2018) and 2019 to evaluate the composition of sports foods available on the market in Australia. The surveys indicated that a number of pre-workout products available on the market may exceed the proposed maximum one-day caffeine quantity. However this dataset is limited, as not all products state what their caffeine content is and were not all sold as FSSF. It is also not clear what proportion of products sold exceed the proposed limit.

All sports foods sold as FSSF (i.e. not sold as therapeutic goods or dietary supplements) containing caffeine would require re-labelling where:

- the current label does not contain a ‘contains caffeine’ statement
- the current label does not declare the caffeine content in the NIP
- the directions for use, if followed, would result in a consumer exceeding the maximum one-day quantity for caffeine from that FSSF.

It is expected that most sports foods sold as FSSF will already have a 'contains caffeine' statement. The option does not prescribe any wording or placement on packaging for this statement and therefore there would be flexibility for businesses in how to make this statement.

Based on the label surveys referred to above, re-labelling is expected to be required to update the NIP and add the proposed advisory statement for a significant number of FSSF that contain caffeine. The total cost to industry of this is unknown. Feedback is required on the number of products affected and the anticipated cost of re-labelling.

Businesses may benefit from certainty about how much caffeine is permitted in FSSF. This may enable more investment in this product category.

Impacts on industry – other foods

Manufacturers, wholesalers and retailers of general foods will be impacted where existing products contain added caffeine (except where current specific permissions apply). Loss of income will occur for businesses who become unable to sell these products.

There are expected to be few, if any, products affected as the Code does not expressly permit the addition of caffeine to food, apart from cola-type drinks and FCBs. As discussed in Section 1.5.2, there are other restrictions within the Code that prevent caffeine being added to foods.

Businesses could apply (using FSANZ's existing processes) for explicit permissions for specific foods for retail sale to contain caffeine within the Code.

Costs to business will occur where an application is submitted, including the cost of developing an application and collecting evidence to support an application. Any application for a caffeinated product could be rejected, which is a risk for businesses. That may slow innovation, trade, sales and profit growth in certain general foods sectors.

Alternatively, businesses could re-categorise a product as a FSSF, subject to that food meeting the requirements of Standard 2.9.4. This would involve re-labelling costs to meet Standard 2.9.4. Reformulation may also be required where the product does not meet the composition requirements for FSSF.

Businesses will have certainty about how caffeine is regulated in foods.

The number of food products expected to be impacted is expected to be small as the addition of caffeine to food is expressly permitted under the Code in two product categories only (cola-type drinks and FCBs). Therefore the total cost impact would be small. However, the impact on individual businesses may be significant.

Consumers – FSSF

As discussed above, the FSSF with caffeine amounts exceeding the proposed maximum one day quantity would either be removed from the market, or else be reformulated and/or relabelled to contain less caffeine per one-day quantity.

This may reduce risks of over-consumption of caffeine for a low and presently unquantified percentage of people who consume FSSF. This is expected to lead to improved health outcomes for a small number of people.

The risk of overconsumption of caffeine from FSSF will be lowered because:

- the quantity per serve of caffeine in some FSSF will reduce, meaning consumers who use these specific products will in many cases have lower caffeine intakes
- it will be clearer what products contain caffeine and given some consumers may not have been aware that certain products contain caffeine, this knowledge may reduce their daily caffeine intake
- displaying the average quantity of caffeine per serving (in the NIP) will give consumers more information to enable them to better manage their daily caffeine intake.

The reduction in overconsumption is limited by the fact that:

- most caffeine consumption currently comes from tea and coffee
- the social science literature review (Section 2.3) has so far found some consumers reporting over-consumption of caffeine (above 400 mg/day) through combining medications and 'sports supplements'. It is unclear whether overconsumption occurs through FSSFs alone. Sports supplements in general include FSSF plus a wide range of other supplements
- the literature review also highlighted that consumers may choose to consume in excess of the recommended limits, regardless of what is recommended (i.e. through taking two or more servings at a time, or through stacking)
- under this option, consumers would still have access to other sports supplements that contain caffeine and are not regulated under the Code, including sports supplements within the definition of therapeutic goods under the TG Act.

The proposed amendment may also have an impact on the range and availability of FSSFs that contain any caffeine, but this impact is currently assumed to be negligible. The impact of this could be loss of choice or reduced performance in activities where caffeine has shown to increase performance. FSSFs with added caffeine would still be permitted with levels below the introduced maximums.

It is also assumed that explicit permissions in the Code for FSSFs to contain caffeine would not markedly increase availability of FSSFs containing caffeine, compared to if no explicit permissions were provided. Stakeholders are invited to comment on this assumption.

Consumers – other foods

It is currently assumed that the range of general foods containing added caffeine available for sale in Australia and New Zealand is limited to few, if any products. That is apart from foods that already contain added caffeine (e.g. FCBs (energy drinks), some FSSF, and cola-type drinks). If these products exist (i.e. products other than FCBs, FSSF and cola-type drinks), consumers will be impacted. FSANZ invites stakeholders to comment on this assumption.

Potential benefits to consumers may be reduced risks of overconsumption of caffeine from food, because of this option's managed permissions approach. This could reduce adverse health outcomes, loss of income from working days lost and other illness costs, particularly for sensitive sub-populations.

Part of the benefits may be reduced risks of consumers unknowingly consuming caffeine in foods or not being aware of how much a food contributes to their recommended maximum daily caffeine intake.

As previously discussed, there is evidence that consumers are not always aware when a product contains caffeine.

Under this option, reduced risks of over-consumption of caffeine may be more relevant to sensitive sub-populations and people who already consume relatively high amounts of caffeine.

Overall, it is unknown by how much this option would reduce risks of caffeine over-consumption on an aggregate basis, given the:

- majority of caffeine consumption currently comes from tea and coffee
- uncertainty about the amounts and ranges of available caffeinated foods that are available on the market (now and in the future) in the absence of this option's managed permissions approach.

FSANZ invites stakeholders to provide comments on the extent that risks of caffeine over-consumption would reduce under this option.

Government

Option 3 would provide greater regulatory certainty for jurisdictions than options 1 or 2.

Cost savings (if any) to the healthcare system from this option are currently assumed to be small. Stakeholders are invited to comment on this assumption.

3.5.1.5 Conclusion

FSANZ has presented what it currently sees as the costs and benefits of each proposed option. FSANZ seeks your feedback and any evidence-based information you can provide for FSANZ to refine these assumed costs and benefits and quantify where possible.

Currently, FSANZ assumes that Option 3 may help reduce over-consumption of caffeine among Australian and New Zealand populations in future.

This option mitigates the risks associated with acute and chronic consumption of caffeine, as the Code will prohibit unless permitted, the addition of caffeine to food. As stated above, this option has no impact on foods such as coffee, tea and chocolate, or the addition of these foods to other foods.

This option may especially help sensitive sub-populations, as caffeine will only be permitted as an added substance in restricted foods, and consumers are generally aware that caffeine is a naturally occurring component of other foods such as tea and coffee. However, it is currently uncertain whether such benefits would outweigh greater costs to industry.

Regulatory certainty would be greatest under Option 3.

FSANZ's assessment is that the direct and indirect benefits that would arise from Option 3 most likely outweigh the associated costs.

3.5.1.6 Questions for stakeholders

Please provide evidence to support your views where possible.

11. How many stock keeping units (SKUs) will be affected by the proposed changes, for either FSSF or other foods, or both?

12. If your business has any SKUs affected, then:
    a. what is the nature of those products, and
    b. what action will you take in response to the regulation (for example, withdraw the product, reformulate the product, update labels to meet new requirements, etc)?

13. What will the cost of the above action(s) be? Be as specific as possible, and please separate the cost by type, for example, reformulation, re-labelling, write-off of existing stock etc.

14. For any of your existing SKUs likely to be affected by the regulatory option, typically how long do those SKUs take to be sold?

15. To what extent do you agree that there are relatively few general foods (i.e. not FSSF) that contain added caffeine (i.e. foods that will be impacted by the proposal) and are currently sold in Australia and New Zealand?

16. Are there any unintended consequences of the proposal?

17. How effective do you believe each of the proposed options would be in achieving the objectives of this proposal and why? In particular, consider risks of over-consumption of caffeine for sensitive sub-populations.

18. Do you have any other comments on the benefits or costs of the proposed options?

3.5.1.7 Other measures

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

3.5.1.8 Any relevant New Zealand standards

New Zealand food law includes the *New Zealand Supplemented Food Standard 2016*. Any impact on this standard will be discussed under the second CFS as this will include the proposed draft variation/s to the Code. For further information, refer to section 2.5.1 of the P1054 Amendment report (FSANZ 2020).

3.5.1.9 Any other relevant matters

Other relevant matters are considered below.

3.5.2 Subsection 18(1)

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

3.5.2.1 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 on-pack advisory statements for certain foods. The assessment indicates that some risks exist to the health and safety of consumers. As stated above, caffeine is a substance that has maximum daily intake recommendations, that vary depending on age and population group.

These assessment findings have informed our preferred approach to amending the Code to explicitly permit total caffeine in FSSF to a maximum one-day quantity of 200 mg in conjunction with appropriate labelling requirements, prohibit the addition of caffeine to foods unless expressly permitted under the Code, and remove the P1054 variation relating to pure and highly concentrated caffeine products. The preferred approach protects public health and safety by limiting the potential for an increase in products containing added caffeine in the food supply.

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

The current advisory statements required for a limited range of products that contain caffeine (see Section 1.5.3 above) assist consumers to make informed choices about foods containing caffeine. FSANZ has also considered advisory statements and labelling of caffeine content on FSSF containing caffeine (see Section 3.2.1.9 above).

3.5.2.3 The prevention of misleading or deceptive conduct

FSANZ has not identified any relevant issues to date.

3.5.3 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 currently available. FSANZ had regard to prior assessments regarding caffeine permissions in the Code (Attachment 1), as well as P1054. Additional information will be sought from stakeholders through this and a second call for submissions to further inform FSANZ's risk analysis.

FSANZ will build upon these findings to inform decisions regarding appropriate regulation of the addition of caffeine to food in the next stage of this work.

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

There are no relevant international food standards relating to addition of caffeine to food.

The assessment considered developments in the regulation of caffeine in other countries (Attachment 2). FSANZ notes however that considerable variation exists between countries in regulations for foods containing added caffeine.

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

The Code currently sets out where there is an express permission to add caffeine to food, being cola beverages and FCBs. A new express permission proposed under this proposal for caffeine in FSSF adds to the Code's provisions.

This issue will be fully considered at the next stage of the assessment and notification will be made in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreements, as necessary.

- **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[4] (now known as the Food Ministers' Meeting). There are three policy guidelines relevant to this application:

- Ministerial Policy Guideline – Regulatory Management of Caffeine in the Food Supply
- Policy guideline – Addition to Food of Substances other than Vitamins and Minerals
- Recommended Policy Guideline on the intent of Part 2.9 – Special Purpose Foods.

FSANZ has had regard to these three policy guidelines as detailed in the following sections. In addition, the high order principles in these three guidelines reflect FSANZ's statutory objectives in subsections 18(1) and 18(2) in the FSANZ Act. FSANZ's assessment in relation to these objectives is described in Sections 2.5.2 and 2.5.3 above.

[4] Available at Food Regulation - Food policies (accessed 21 November 2022)

Ministerial Policy guideline – Regulatory Management of Caffeine in the Food Supply

The Specific Policy Principles are in this guideline are that the regulatory management of caffeine in the food supply should:

a) be based on risk analysis ensuring consideration of general population and taking into account vulnerable population groups including children, adolescents, pregnant and lactating women and caffeine sensitive consumers;
b) consider exposure to caffeine from all dietary sources; and
c) be informed by emerging evidence and the regulation of caffeine in overseas jurisdictions.

Additional Policy Guidance:

- FSANZ is encouraged to work with research agencies to monitor caffeine consumption across the population, including consumption by vulnerable population groups.
- Regulatory management of caffeine in the food supply may include regulatory and non-regulatory risk management approaches.

As outlined in this report, SD 1 and SD 2, FSANZ has had regard to the above policy principles and guidance.

Policy Guideline – Addition to Food of Substances other than Vitamins and Minerals

This policy guideline does not apply to special purpose foods including FSSF but does apply to other foods within the scope of this proposal.

This policy guideline includes Specific Order Policy Principles for substances added solely for a technological function as well as for any other purpose.

The Specific Order Policy Principles for 'technological function' state that the addition of substances other than vitamins and minerals to food should be permitted where:

a) the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose'); and
b) the addition of the substance to food is safe for human consumption; and
c) the amounts added are consistent with achieving the technological function; and
d) the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and
e) no nutrition, health or related claims are to be made in regard to the substance.

The Specific Order Policy Principles for 'any other purpose' state that the addition of substances other than vitamins and minerals to food should be permitted where:

a) the purpose for adding the substance can be articulated clearly by the manufacturer (i.e. the 'stated purpose')
b) the addition of the substance to food is safe for human consumption
c) the substance is added in a quantity and a form which is consistent with delivering the stated purpose
d) the addition of the substance is not likely to create a significant negative public health impact to the general population or sub-population
e) the presence of the substance does not mislead the consumer as to the nutritional quality of the food

FSANZ has had regard to these policy principles as outlined in this report, in particular Section 3.2.2, and in SD 1.

Policy guideline on the intent of Part 2.9

This policy guideline applies to the consideration of the regulation of caffeine in FSSFs. The specific policy principles are:

- Special purpose foods should be targeted only to those population groups satisfying the definition presented in the Scope/Aim section.
- The composition of special purpose food should be consistent with the intended purpose.
- Adequate information should be provided, including through labelling and advertising of special purpose foods, to:
- assist consumer understanding of the specific nature of the food, the intended population group and intended special purpose of the food; and
- provide for safe use by the intended population and to help prevent inappropriate use by those for whom the special purpose food is not intended.
- Consideration, where appropriate, should be given to application of controls to restrict access to a special purpose food on the basis of risk to public health and safety.

As outlined in this report, in particular Section 3.2.1, FSANZ has had regard to the above policy principles.

The policy guideline requires assessment of both the safety and consistency of composition with intended purpose. The definition of FSSF currently refers to assisting sports people in achieving specific nutritional or performance goals, providing the 'intended purpose' at a broad level. The assessment of caffeine and sports performance aimed to assess the effect of caffeine on aerobic exercise performance in the general healthy population, including trained athletes and untrained individuals (SD 4).

Following assessment as outlined in this report, FSANZ has determined that setting of a maximum one-day quantity for FSSFs and an express prohibition on the addition of caffeine to other foods unless expressly permitted would be consistent with the above specific policy principles. As already stated, the setting of a one-day quantity for caffeine added to a FSSF is consistent with the permissions for added substances already contained in Standard 2.9.5 – Formulated Supplementary Sports Foods. This approach recognises that FSSF are special purpose foods, and in the case of FSSF, are 'a product this is specifically formulated to assist sports people in achieving specific nutritional or performance goals.'

4 Implementation

4.1 Transition

A transition period for implementation of any new requirements will be considered at the next stage of the assessment and consulted on during the second call for submissions.

4.2 Education

Recommendation 3 of FSANZ's 'Pure and highly concentrated caffeine products report' proposed an inter-agency consumer information campaign on safe caffeine consumption. Consumer education materials on the dangers of pure and highly concentrated caffeine products have been developed in response to recommendation 3 of the Report[5].

Additional educational resources would be developed for consumers and the food industry subject to the outcome of this proposal.

5 References

ANZFA 2001. Application A394 - Formulated Caffeinated Beverages (Energy Drinks).

Barone JJ, Roberts HR. 1996. Caffeine consumption. Food Chem Toxicol 34:119–29.

BfR (2019) Children and adolescents: Excessive consumption of energy drinks Increases health risk for cardiovascular system https://www.bfr.bund.de/cm/349/children-and-adolescents-excessive-consumption-of-energy-drinks-health-risk-for-cardiovascular-system.pdf. Accessed 15 September 2022

Conger SA, Warren GL, Hardy MA, Millard-Stafford ML (2011) Does caffeine added to carbohydrate provide additional ergogenic benefit for endurance? Int J Sport Nutr Exe 21:71–84 Desbrow B, Hall S, O'Connor H,Slater G, Barnes K, Grant G (2018) Caffeine content of pre-workout supplements commonly used by Australian consumers. DrugTest Anal. 2018;1–7.https://doi.org/10.1002/dta.2501

Doherty M, Smith PM (2004) Effects of caffeine ingestion on exercise testing: a meta-analysis. Int J Sport Nutr Exe 14:626–646

EFSA (2015) Scientific opinion on the safety of caffeine. EFSA Journal 2015;13(5):4102 https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4102. Accessed 15 September 2022

European Commission (2018) Commission Regulation EU 2018/1482 of 4 October 2018 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards caffeine and theobromine. Accessed 15 September 2022

European Commission (2020) European Commission list of flavouring substances. Caffeine, flavouring number FL 16.016. Accessed 15 September 2022

FCC (2018) Food Chemicals Codex 12 - page 182. Food Chemicals Codex (FCC) | FCC | Online. Accessed 9 September 2022

FCI 2021. (Food Compliance International). https://www.foodcomplianceinternational.com/ Accessed 9 September 2022

[5] Available on the FSANZ website at https://www.foodstandards.gov.au/consumer/generalissues/Pages/highly-concerntrated-caffeine.aspx

Ferreira RES, Pacheco RL, de Oliveira Cruz Latorraca C, Riera R, Eid RG, Martimbianco ALC (2021) Effects of caffeine supplementation on physical performance of soccer players: systematic review and meta-analysis. Sports Health. 13:347-358

FRSC 2013. Review of the Australian and New Zealand Ministerial Council policy guideline on the addition of caffeine to foods. Accessed 9 September 2022

FRSC 2014. Food Regulation - Policy guideline on the addition of caffeine to foods. Accessed 9 September 2022

FRSC 2018. Sports Supplements Roundtable: Report on Discussions and Next Steps. Accessed 9 September 2022

FSANZ 2000 Expert Working Group on The Safety Aspects of Dietary Caffeine. https://www.foodstandards.gov.au/publications/Documents/safety%20aspects%20of%20dietary%20caffeine.pdf

FSANZ 2019. FSANZ report to Ministers on Pure and highly concentrated caffeine products.

FSANZ 2020. P1054 – Pure and highly concentrated caffeine products.

Grgic J, Grgic I, Pickering C, Schoenfeld BJ, Bishop DJ, Pedisic Z (2020) Wake up and smell the coffee: caffeine supplementation and exercise performance—an umbrella review of 21 published meta-analyses. Brit J Sport Med 54:681-688

Heckman, M.A., Weil, J. and De Mejia, E.G. (2010), Caffeine (1, 3, 7-trimethylxanthine) in Foods: A Comprehensive Review on Consumption, Functionality, Safety, and Regulatory Matters. Journal of Food Science, 75: R77-R87. https://doi.org/10.1111/j.1750-3841.2010.01561.x

Jagim AR, Camic CL and Harty PS (2019) Common habits, adverse events, and opinions regarding pre-workout supplement use among regular consumers. Nutrients 11, 855; doi:10.3390/nu11040855

National Cancer Institute (2021) Usual dietary intakes. https://epi.grants.cancer.gov/diet/usualintakes/. Accessed 9 September 2022

NCBI (2022). PubChem Compound Summary for CID 2519, Caffeine. https://pubchem.ncbi.nlm.nih.gov/compound/Caffeine. Accessed 9 September 2022

Office for Sport – Department of Health, KPMG Sports Advisory (2020) Sports industry economic analysis: exploring the size and growth potential of the sport industry in Australia. https://www.health.gov.au/resources/publications/sports-industry-economic-analysis. Accessed 26 November 2022

Ribeiro BG, Morales AP, Sampaio-Jorge F, Tinoco F de S, de Matos AA, Leite TC (2017) Acute effects of caffeine intake on athletic performance: a systematic review and meta-analysis. Revista Chilena De Nutrición 44:283–291

Scott CC, Brown Robins E., Chen KK (1949) Synthetic Caffeine. Science14 Feb 1947 : p176. DOI: 10.1126/science.105.2720.176

Sempos CT, Looker AC, Johnson CL, Woteki, CE (1991) The importance of within-person variability in estimating prevalence. Chapter 9 in Monitoring Dietary Intakes, ILSI Monographs, ed I Macdonald, Springer-Verlag, Heidelberg

Shen JG, Brooks MB, Cincotta J, Manjourides JD (2019) Establishing a relationship between the effect of caffeine and duration of endurance athletic time trial events: a systematic review and meta-analysis. J Sci Med Sport 22:232–238

Southward K, Rutherfurd-Markwick KJ, Ali A (2018) Correction to: The effect of acute caffeine ingestion on endurance performance: a systematic review and meta-analysis. Sports Med 48:2425–2441

USFDA (2018) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-highly-concentrated-caffeine-dietary-supplements. Accessed 4 November 2022

USFDA 2020 eCFR — Code of Federal Regulations 21 CFR Accessed 15 September 2022

ATTACHMENT 1

History of caffeine regulation in Australia and New Zealand

Timeline of caffeine regulation

Pre-2001	Only permission in the Australia New Zealand Food Standards Code (the Code) to add caffeine to food was in the context of caffeine as a food additive (flavouring) in cola-type drinks
2001	Standard 2.6.4 – Formulated Caffeinated Beverages was gazetted (ANZFA 2001).
April 2003	On 4 April 2003 the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) (now known as the Food Ministers' Meeting) agreed to a policy guideline on the addition of caffeine to foods. The Forum agreed, until further evidence became available, to maintain the status quo for caffeine regulation by: • maintaining the current additive permissions for caffeine; and • restricting the use of new products containing non-traditional caffeine rich ingredients (including guarana) to boost the caffeine content in other food, beyond the current provisions for caffeine.
May 2011	On 6 May 2011 the Forum agreed to a comprehensive review of the 2003 policy guideline, noting the increased number of energy drinks on the market containing caffeine and other exotic ingredients.
September 2013	The Food Regulation Standard Committee (FRSC) released a Consultation Paper for public consultation on a Food Regulation Policy Options Paper for formulating policy guidelines on the regulation of caffeine in the Australian and New Zealand food supplies (FRSC 2013).
June 2014	The Forum agreed to a new policy guideline on the regulatory management of caffeine in the food supply (FRSC 2014).
July 2018	On 24 July 2018, a roundtable on sports supplements was convened by the Australian Government Department of Health on behalf of FRSC. The roundtable consisted of consumer groups, the sports supplement industry, health professionals, the Australian Government and state and territory governments (FRSC 2018).
July 2019	Senator the Hon Richard Colbeck together with Minister Hunt requested Food Standards Australia New Zealand (FSANZ) to provide information about current caffeine permissions in the Code and preliminary recommendations for strengthening regulations and consumer warnings for caffeine powders and high caffeine content products by the end of August 2019 (FSANZ 2019).
December 2019	The Code was varied to prohibit total caffeine present in a concentration of 1% or more for liquid foods and 5% or more for solid and semi-solid foods for retail sale. The variation was prepared and approved as part of an Urgent Proposal P1054 – Pure and highly concentrated caffeine products, under Sub-Division A of Division 4, Part 3 of the *Food Standards Australia New Zealand Act 1991* (the Act) (FSANZ 2020).
December 2020	Proposal P1056 was prepared to consider whether additional measures are required in relation to caffeine 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 vulnerable sub-populations and whether and how any such risk should best be managed.

ATTACHMENT 2

Regulation of caffeine internationally

United states of America (USA)

In the USA, additives such as caffeine must be used in accordance with food additive regulation which specifies the conditions under which it must be used. However, such regulation is not needed if the substance is 'generally recognized as safe' (GRAS) (i.e. substances generally recognised to be safe by qualified experts). The FDA Code of Federal Regulations[1], states that caffeine is GRAS when used in cola-type drinks and that the level of caffeine in these types of beverages must not exceed 0.02 per cent (i.e. 200 ppm).

Caffeine may also be used as an ingredient in other foods provided it has been determined as GRAS for its intended use in those foods. To date, no GRAS determinations for caffeine-containing ingredients have been located via an internet search and there are none listed on the USA inventory of GRAS notices, except for *Illex guayusa* leaf extract[2].

Any food that contains added caffeine must have caffeine listed as an ingredient, but the actual quantity of caffeine does not have to be stated on the label. There are no other labelling requirements specifically for caffeine in the USA[3].

Canada

The addition of caffeine to food is regulated as a food additive. Carbonated soft drinks can contain caffeine, i.e. cola-type drinks up to 200 ppm and non-alcoholic carbonated water-based flavoured and sweetened beverages other than cola-type drinks up to 150 ppm[4]. Requests to add caffeine to foods such as snacks have not been accepted to date (personal communication).

As a food additive, caffeine would need to be declared in the list of ingredients[5]. No quantitative labelling is required however manufacturers are encouraged to label the amount of caffeine per stated serving size[6]. This does not apply to foods/ingredients that are well known sources of caffeine (e.g. coffee, tea and chocolate). There is no regulatory requirement to identify the presence of or amount of caffeine for natural sources of caffeine.

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[1] 21CFR182.1180 available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=182.1180 Accessed 9 September 2022

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

[3] Leah S Rosenfeld, Jeremy J Mihalov, Susan J Carlson, Antonia Mattia, 2014. Regulatory Status of caffeine in the United States. Nutrition Reviews, Volume 72, Issue supple 1, 1 October 2014, pp 23-33

[4] List of Permitted Food Additives with Other Accepted Uses (Lists of Permitted Food Additives) available at https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/8-other-accepted-uses.html incorporated by reference in the Marketing Authorization for Food Additives with Other Accepted Uses, enabled by the Food and Drugs Act. Accessed 9 September 2022

[5] Food and Drug Regulations B.01.008 available at https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-5.html#docCont Accessed 9 September 2022

[6] Preliminary Guidance for Industry on the Labelling of Caffeine Content in Prepackaged Foods (March 2010) available at https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/preliminary-guidance-industry-labelling-caffeine-content-prepackaged-foods-march-2010.html Accessed 9 September 2022

Health Canada intends to consult in the next few months on making quantitative caffeine labelling a required condition of use of any food additive caffeine (this would be applicable to carbonated soft drinks) (personal communication).

European Union

The use of caffeine as a flavouring substance in food is subject to restrictions of use in certain food categories (dairy products and analogues 70 mg/kg, edible ices 70 mg/kg, confectionery 100 mg/g, non-alcoholic beverages 150 mg/kg)[7].

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

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

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

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

In 2018 the UK government consulted on ending the sale of energy drinks to children[8]. According to media reports (July 2019), the government has confirmed it will ban the sale of energy drinks to children under 16.

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

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

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

Summary table of international caffeine regulation

Region	Foods with added caffeine
Poland	Maximum caffeine: 200 mg per portion, with a total of 400 mg/day from all sources Furthermore, caffeine containing supplements should include an indication on the label regarding the contribution of caffeine in relation to maximum daily intake and a warning that it is not recommended for children and pregnant women, and that it should not be consumed with other sources of caffeine or other stimulating substances (FCI 2021).
Mexico	If the pre-packaged product contains added caffeine within the list of ingredients in any quantity, the front-of-pack label must bear the warning statement, "CONTAINS CAFFEINE — CHILDREN SHOULD AVOID", which should appear in the upper right part of the main display surface. FSANZ understand there are no compositional limits or labelling requirements specifically for caffeine
Argentina	Energy drinks should be named as "Soft drinks with caffeine and taurine", and when these contain vitamin and/or minerals exceeding the RDIs and/or authorised herbs, this should be specified as "supplemented with caffeine and taurine, vitamins and/or minerals" (FCI 2021).
Uruguay	Formulas containing added caffeine, except for ingredient sources that naturally contain it (with a limit for naturally containing caffeine of 20 mg per 100 g/ml.) do not fall under the scope of supplements for sports people (Ferreira 2021). There is a limit for foods in which caffeine is naturally present, of 20 mg per 100 g/ml.
USA	Caffeine may be used as an ingredient in foods provided it has been determined as Generally Recognised as Safe. No labelling requirements specifically for caffeine.
Canada	Addition of caffeine regulated as a food additive. Permitted in some beverages up to specified limits. Specific labelling requirements for caffeinated energy drinks. No compositional limits or regulatory requirement to identify the presence of or amount of caffeine for natural sources.
European Union	Use of caffeine as a flavouring substance in food is subject to restrictions of use in certain food categories. No compositional rules if added for a nutritional or physiological effect. Specific warnings required for caffeine. The actual caffeine content must also be on the label. For foods with naturally occurring caffeine, specific warnings are required for some foods, excluding beverages based on coffee, tea or coffee or tea extract where the name of the food includes the term 'coffee' or 'tea'.