15 December 2020
[145-20]

Amendment of the approved variation **– Urgent Proposal P1054**

Pure and highly concentrated caffeine products

On 12 December 2019, FSANZ 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. That variation to the Code took effect on 12 December 2019 in Australia and on 3 February 2020 in New Zealand

The variation was prepared and approved as part of Proposal P1054, which had been declared as an Urgent Proposal under section 95 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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

After considering all submissions received, FSANZ decided to prepare a proposal for the further variation of the Code in relation to caffeine. This report sets out the reasons for that decision and is provided pursuant to section 101 of the FSANZ Act.

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The following documents informed the assessment of this Proposal and are available on the FSANZ website:

- Final Consideration Report – Urgent Proposal P1054 – Pure and highly concentrated caffeine products.
- SD1 Risk and technical assessment – Urgent Proposal P1054 – Pure and highly concentrated caffeine products.

Executive summary

On 12 December 2019, the FSANZ Board approved a variation (the variation) to Standard 1.1.1 of the Australia New Zealand Food Standards Code (the Code) to '*prohibit the retail sale of pure and highly caffeinated products*.' The approved variation and its prohibition took effect on 12 December 2019 in Australia and on 3 February 2020 in New Zealand.

The variation was approved as an emergency interim response following FSANZ's review and report to Australian Government Ministers in August 2019. Ministers had requested the review after the death of a young man in New South Wales attributed to acute caffeine toxicity associated with the consumption of a highly concentrated caffeine powder. The review found pure and highly caffeinated products pose an immediate and acute risk to consumers. The ingestion of small amounts of these substances can result in severe health effects, including death.

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).

The Act required FSANZ to assess the variation and then either reaffirm the decision to approve the variation or prepare a proposal to develop a further variation. The Act required this to happen within 12 months of the variation taking effect (i.e., by 12 December 2020).

The Act also required FSANZ to call for public submissions after making the above assessment, but before making the above decision. FSANZ assessed the variation in accordance with section 99 of the FSANZ Act and then called for public submissions on 28 July 2020.

In the call for public submissions, and based on its assessment, FSANZ's preferred option was to prepare a proposal under the Act 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,

- 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.

After considering all submissions received, FSANZ decided to prepare a new proposal.

1 Introduction

1.1 Background

In August 2019, FSANZ undertook a review and provided a report to Australian Ministers that made five recommendations (Attachment C) for strengthening regulations and consumer warnings in relation to pure and highly concentrated caffeine products.[1] The review was undertaken at the request of Australian Government Ministers and in response to the death of a young man in New South Wales attributed to acute caffeine toxicity associated with the consumption of a highly concentrated caffeine powder.

The first recommendation was that FSANZ develop and declare as urgent a proposal to amend the Australia New Zealand Food Standards Code (the Code) 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. The proposal was prepared under FSANZ's urgent legislative provisions.

FSANZ undertook public consultation on the urgent proposal from 1 to 14 November 2019 (due to the urgent nature a 14 day consultation period was undertaken). The submissions are available on the FSANZ website.

In December 2019, for the reasons detailed in the Final Consideration Report, the FSANZ Board approved a variation to the Code to prohibit the retail sale of pure and highly concentrated caffeine products. That is, 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). The approved variation took effect on 12 December 2019 in Australia and on 3 February 2020 in New Zealand, and is at Attachment A.

The approved variation was based on FSANZ's risk assessment that identified the concentrations of caffeine above which are likely to result in serious acute adverse health effects on consumers.

The approved variation has met its objective of protecting consumers of pure and highly concentrated caffeine products by placing a prohibition on products that posed the highest risk. It was not, and is not, intended to address broader issues related to the use of or presence of caffeine in food more generally.

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

1.2 The approved variation

The approved variation requires that, unless expressly permitted, a food for sale must not be a food in which caffeine is present at a concentration of 1% or more (1,000 mg/100 mL,) if the food is a liquid form, or 5% (5,000 mg/100g), if the food is a powder, gel or other dry form. A copy of the approved variation is at Attachment A.

[1] The Food Standards Caffeine Report 2019

The regulatory regime governing caffeine is detailed in FSANZ's report to Ministers.

The Code provisions relevant to caffeine as amended by the approved variation are detailed in section 1.2.2 of the Call for Submissions.

The measures governing the importation of food into Australia containing caffeine are detailed in sections 1.3 and 1.4 of the Call for Submissions.

Section 1.6 of the Call for Submissions explains how the laws in Australia governing food and therapeutic goods interact in regulating caffeine and how that interaction is managed. Section 1.6 also details action being taken by the Therapeutic Goods Administration (TGA) in relation to therapeutic goods containing caffeine.

1.3 Scope

The scope of P1054 addressed Recommendation 1 of the Ministers' report to '*prohibit the retail sale of pure and highly concentrated caffeine products*'. The approved variation was not intended or designed to address broader issues related to the use or presence of caffeine in the food supply more generally.

A Working Group[2] established by FSANZ agreed the availability of pure and highly concentrated caffeine products for retail sale posed an unacceptably high risk to consumers and should be considered urgently and separately to other products containing caffeine (refer to Executive Summary of the FSANZ Report to Ministers).[3]

2 Summary of the assessment of the variation

FSANZ's assessment of the variation was detailed in the call for submissions issued by FSANZ on 28 July 2020.

The call for submissions noted that:

- the risk assessment concluded that there was an immediate and acute risk posed by the sale of pure or highly purified forms of caffeine to consumers; ingestion of small amounts of these substances can result in severe health effects, including death;
- the decision to prohibit pure and highly concentrated caffeine products was warranted;
- that there is a need to consider wider issues, in particular:
  - the extent of the risk posed to sensitive subpopulations by caffeine in the food supply, and
  - whether and how any such risk should be managed.

[2] In developing its report to Ministers, FSANZ established a working group with representatives from Commonwealth agencies (the Department of Health, the Therapeutic Goods Administration (TGA) and the then Department of Agriculture), food regulatory authorities from the States and Territories and New Zealand's Ministry for Primary Industries and New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

[3] The Foods Standards Caffeine Report 2019

The Call for Submissions proposed three possible risk management options:

- Option 1: reaffirm the approved variation
- Option 2: prepare a proposal to repeal the approved variation; meaning the measure is no longer warranted
- Option 3: prepare a proposal to amend and/or add to the approved variation.

FSANZ preferred Option 3 – as stated in the Call for Submissions, which was to prepare a proposal under section 55 of the FSANZ Act to consider further variations to the Code in relation to caffeine in the Australian and New Zealand food supply.

FSANZ also noted such a proposal could consider the regulation of caffeine in sports foods and whether a maximum limit on caffeine for foods in the general food supply is necessary.

The Code's regulation of sports foods is currently being reviewed by FSANZ under Proposal P1010, which is a review of Standard 2.9.4 –Formulated Supplementary Sports Foods. The second recommendation of FSANZ's review report to Australian Government Ministers 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'* and have a focus on caffeine in sports food, currently being reviewed under P1010.

This recommendation, which was accepted by Australian Government Ministers, indicates that sports foods, which currently do not have a maximum level specified in the Code, are likely to be a major dietary source of added caffeine. On this basis, it would be prudent to consider the issue of caffeine in sports foods under the auspices of a new caffeine proposal. As Standard 2.9.4 is the target regulation, the consistency of the intended purpose of addition of caffeine to sports food would also need to be considered. Any limit for sports foods could potentially form the basis of a general limit in the Code, taking into account recent changes in regulation of therapeutic goods in Australia (see below).

2.1 Summary of issues raised

Public submissions were invited on the assessment of the variation which was released for public comment from 28 July to 11 September 2020. Eighteen submissions and one late comment were received.

In the Call for Submissions, FSANZ proposed the following three risk management options:

- Option 1: reaffirm the approved variation
- Option 2: prepare a proposal to repeal the approved variation; meaning the measure is no longer warranted
- Option 3: prepare a proposal to amend and/or add to the approved variation.

As mentioned above, the Calls for Submission stated that Option 3 was FSANZ's preferred option.

The majority of submitters supported Option 3. In summary:

- Jurisdictions (7 in total) supported Option 3 and provided information to justify this preference, including suggestions on the scope of a new proposal

- Industry (5 in total) supported Option 1 and indicated the current variation permitted the current range of products and would accommodate future product development needs

- Dietitian Associations (4 in total) supported Option 3 and indicated the levels of caffeine in sports foods need to be addressed in addition to a restriction on the sale of caffeinated products to consumers under 18 years of age

- Complementary Medicines Australia (CMA) supported Option 3 and requested more prescriptive label warnings for sensitive sub-populations and support for stipulating the number of doses per day. CMA support a whole of government Approach, with TGA to provide harmonisation between foods and listed medicines

- A private submitter supported Option 3, suggesting improving labelling in line with dietary supplements

- A late comment from an independent food manufacturer, who support Option 2 as the variation would prohibit the sale of their current product range.

Attachment E summarises the issues raised in submissions and FSANZ's response to those issues.

2.2 Section 7 declaration under the Therapeutic Goods Act

As mentioned above, section 1.6 of the Call for Submissions details how the laws in Australia governing food and therapeutic goods interact in regulating caffeine and how that interaction is managed. Section 1.6 details the action being taken by the Therapeutic Goods Administration in relation to therapeutic goods containing caffeine.

After public consultation on Proposal P1054 closed, a declaration was made under section 7 of the *Therapeutic Goods Act 1989* (the TG Act), that certain sports supplements are therapeutic goods for the purposes of that Act. The declaration was made on 23 September 2020 and came into effect on 30 November 2020.

The declaration provides that goods that meet the following criteria are 'therapeutic goods' and subject to regulation under the TG Act if:

Goods for oral administration that are represented (expressly or by implication) as being for the improvement or maintenance of physical or mental performance in sport, exercise or recreational activity, and that:

a) contain, or are represented (expressly or by implication) to contain, one or more of the following substances (however described or named):

    i. a substance included in a schedule to the current Poisons Standard; or

    ii. a substance expressly identified on the Prohibited List that is added as an ingredient to the goods; or

    iii. a relevant substance that is added as an ingredient to the goods; or

    iv. a substance with equivalent pharmacological action to a substance mentioned in subparagraph (i), (ii) or (iii), including those that may be

characterised as an active principle, precursor, derivative, salt, ester, ether or stereoisomer; or

b) on or after 30 November 2020 are supplied in the dosage form of a tablet, capsule or pill other than those goods containing glucose only when the goods are used, advertised, or presented for supply:

    a) for therapeutic use; or

    b) in a way that is likely to be taken to be for therapeutic use; including, but not limited to, one or more of the following therapeutic uses:

    c) gaining muscle;

    d) increasing mental focus;

    e) increasing metabolism;

    f) increasing stamina;

    g) increasing testosterone levels, reducing oestrogen levels or otherwise modifying hormone levels;

    h) losing weight or fat;

    i) preparing for workout;

    j) recovering from workout

As explained in the Call for Submissions, caffeine is a substance that is scheduled in the Poisons Standard. Caffeine, when the use is for internal therapeutic use, has been placed in Schedule 4 (prescription only medicines) of the Poisons Standard except:

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

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

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

As a result, caffeine containing sports foods, which meet the requirements of the section 7, are now 'therapeutic goods' for the purposes of the TG Act, and the provisions of the FSANZ Act and the Code do not apply. It is important to note that these legislative changes are only applicable to sports foods available in Australia.

2.3. Decision

Section 101 of the FSANZ Act requires 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.

Section 101 requires the above to occur within 12 months of the date that the P1054 variation came into effect. That is, by 12 December 2020.

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

FSANZ's risk assessment concluded that there was an immediate and acute risk posed by the sale of pure or highly purified forms of caffeine to consumers. FSANZ's assessment and conclusion remains that the prohibition imposed by the approved variation protects consumers from products that posed the highest risk and is warranted. In that regard, this Proposal's objective has been met.
However, for the reasons stated in this report and in the Call for Submissions, FSANZ decided to prepare a proposal under the Act 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,

- caffeine in sports food and the need to consider establishing 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 managed.

The approved variation will remain unchanged and in force until and unless amended as a result of and at the completion of the new proposal. This ensures ongoing protection of consumers from pure and highly concentrated caffeinated products.

The variation, as it appeared in the final consideration report, is at Attachment A. The related explanatory statement is at Attachment B.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the proposal and the impacts of regulatory options.

Public submissions were invited on the assessment of the variation, which was released for public comment from 28 July to 11 September 2020. The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media tools and digital newsletter - Food Standards News. Subscribers and interested parties were also notified.

2.3.2 World Trade Organization (WTO)

In developing and reviewing food standards, both FSANZ and the Forum must have regard to whether those standards are consistent with the obligations of both Australia and New Zealand under the Agreement establishing the World Trade Organization (WTO).

As WTO members, Australia and New Zealand are also 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. The measure was notified in December 2019 after the public notice of the urgent measure. No submissions were received from WTO Members.

2.5 FSANZ Act assessment requirements

2.5.1 Section 99

Section 99 of the Act required FSANZ to have regard to certain specific matters when assessing the variation. These considerations are summarised below.

- **whether the costs that have arisen, or will arise, from the variation outweigh the direct and indirect benefits to the community, government or industry that have arisen, or will arise, from the variation**

FSANZ concluded in the Final Consideration Report that the benefits of the approved variation were likely to outweigh the costs.

FSANZ's subsequent assessment of the approved variation reached the same conclusion, but noted that preparation of a proposal (Option 3 in the Call for Submissions) and the consideration of further amendments may assist in identifying and determining net benefit. As stated in the Call for Submissions, assessments undertaken as part of a new proposal, including of the merits of amending the approved variation, would be informed by a Regulatory Impact Statement (RIS) in accordance with best practice.

FSANZ's conclusion remained unchanged after consideration of all submissions and comments.

- **whether other measures (available to FSANZ or not) would be more cost-effective than the variation**

For the reasons stated above, and after consideration of all submissions, FSANZ remains satisfied that a prohibition is likely to be the most cost-effective food regulatory measure to address the risk posed by pure or highly concentrated caffeine products. Preparation of a proposal will allow further consideration of the costs and impact of the approved variation and any alternatives, including whether there are other more cost effective measures. During that process a full regulatory impact statement will be prepared.

- **any relevant New Zealand standards**

The amendment made under the approved variation to Standard 1.1.1 of the Code applies in both Australia and New Zealand.

New Zealand food law includes the *New Zealand Supplemented Food Standard 2016*, the operation of which is explained in section 1.4.1 of the Call for Submissions. The new provision in section 1.1.1—10 and its prohibition introduced by the approved variation will apply to supplemented foods under the *New Zealand Supplemented Food Standard 2016.*

- **any other relevant matters, including FSANZ's statutory objectives in standards development**

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

FSANZ had regard to the three objectives in subsection 18(1) of the FSANZ Act during the assessment and in making its decision to prepare a new proposal.

2.5.2.1 Protection of public health and safety

The FSANZ Act requires FSANZ to have regard to the fact that the primary objective in standards development is the protection of public health and safety. FSANZ concluded that a prohibition as provided by the variation best addressed the risk posed by pure and highly caffeinated products. However, an assessment of the risks associated with the consumption of caffeine in sports foods, and the extent of the risk to sensitive subpopulations, still needs consideration, hence the decision to prepare a proposal to assess such risks.

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

There are no proposed additional labelling measures being considered in this proposal (P1054) to protect consumers from pure and highly concentrated caffeine products. FSANZ's assessment was that other measures (for example, mandatory labelling/warning statements) are unlikely to protect public health and safety for these specific products. The new proposal will however, consider whether risk management measures for foods containing caffeine more generally are required.

2.5.2.3 The prevention of misleading or deceptive conduct

After a comprehensive assessment and consideration of submissions, FSANZ's view remains that the prohibition imposed by the approved variation protects consumers unaware of the risks of pure and highly concentrated caffeine products, thereby supporting the objective of prevention of misleading or deceptive conduct. However, as mentioned above, the new proposal provides an opportunity to consider whether additional risk management measures for foods containing caffeine more generally are required.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

The variation was based on and reflects a risk assessment that relied on the best available scientific evidence. FSANZ's risk assessment evaluated and characterised the risk from the consumption of pure and highly concentrated caffeine products. The risk analysis considered currently available information (national and international), including animal and human toxicity, relevant to the safety of pure and highly concentrated caffeine products.

FSANZ's risk assessment remains unchanged after consideration of all submissions and comments received following the Call for Submissions.

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

International approaches to the regulation of caffeine were detailed in section 1.5 of the Call for Submissions. As shown therein, there are no consistent international standards for caffeine, nor is there a consistent approach internationally to regulating caffeine.

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

Australia and New Zealand's reputation as a producer of safe food is an important factor in being regarded as an efficient and internationally competitive food industry.

There are no relevant international standards and amending the Code to prohibit the sale of pure and highly concentrated caffeine products is unlikely to have a significant effect on international trade because these highly specialised products comprise a very small segment of the market.

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

No fair trading issues have been identified for the purposes of this Proposal.

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

The Forum (then convening as the Australia and New Zealand Food Regulation Ministerial Council) agreed to an amended Policy Guideline on the regulatory management of caffeine in the food supply in June 2014[4].

FSANZ had regard to the Ministerial Policy Guidelines for the Regulatory Management of Caffeine in the Food Supply.

The Department of Health and the Food Regulation Standing Committee (FRSC) Senior Project Officer have completed an audit of the policy guidelines, with recommendations. FRSC has identified an update of the caffeine Guideline as priority work for FRSC.

If the updated policy guideline is available, it will provide valuable policy direction for FSANZ's future work on caffeine in the food supply.

Attachments

A. Approved variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement
C. The five recommendations of the Ministers' report
D. Declaration of urgency
E. Summary of submissions
F. Summary of suggested scope for new proposal

[4] Ministerial Policy Guidelines for the Regulatory Management of Caffeine in the Food Supply

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

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

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The Board of Food Standards Australia New Zealand gives public notice of the approval of this variation under section 97 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated 11 December 2019

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

Note:

Public notice of the approval of the variation will be given in the *Food Standards Australia New Zealand Notification Circular* Number 105-19 published and issued on 12 December 2019. This means that this date is the date of public notice for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1054 – Pure and highly caffeinated products) Variation*.

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

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

3 Commencement

The variation commences on the date of public notice of the approval of the variation.

4 Transitional arrangements

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

Schedule

[1] **Standard 1.1.1** is varied by omitting paragraph 1.1.1—10(5)(f), substituting

(f) if the food is for retail sale—raw apricot kernels;

(g) if the food is for retail sale—a food in which caffeine is present at a concentration of:

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

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

Attachment B – Explanatory Statement

1. Authority

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

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

The Authority prepared Proposal P1054 to amend the Code to prohibit the retail sale of pure and highly concentrated caffeine products.

Following its preparation, Proposal P1054 was declared an Urgent Proposal for the purposes of the Division 4 of Part 3 of the FSANZ Act.

The Authority considered the Proposal in accordance with sections 96 and 97 of the FSANZ Act and has approved a variation.

2. Purpose

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

3. Documents incorporated by reference

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

4. Consultation

The Authority considered the Proposal in accordance with the procedure in Division 4 of Part 3 of the FSANZ Act. That consideration included one round of public consultation following an initial consideration and the preparation of a draft variation and associated assessment summary. After that public consultation, the Authority had regard to all submissions received and approved an amended version of the draft variation.

The approved variation must be reviewed by the Authority within 12 months of its notification in accordance with Subdivision B of Division 4 of Part 3 of the FSANZ Act. Further public consultation is required as a part of that assessment.

A Regulation Impact Statement was not required. The Authority submitted a preliminary assessment to the Office of Best Practice Regulator (OBPR) seeking advice on a regulatory intervention in relation to Proposal P1054. On 4 October 2019, the OBPR advised the Authority that a COAG Regulation Impact Statement was not required to inform the decision by the Authority to approve, amend or reject the draft variation.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1.1] amends Standard 1.1.1 by inserting a new paragraph into subsection 1.1.1—10 (5).

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

- 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.

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

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

The reference to ‘caffeine’ in paragraph 1.1.1—10 (5)(g) includes caffeine that occurs or is present in the food for sale naturally. The exception provided by subsection 1.1.1—10(7) of the Code for foods (such as caffeine) that occur or are present in the food for sale naturally does not apply to a prohibition imposed by subsection 1.1.1—10(5) and, therefore, to the prohibition imposed by the new paragraph.

The new paragraph cannot - and does not – itself constitute a permission for the purposes of the Code to add caffeine to all foods (e.g., for the purposes of the prohibitions imposed by other paragraphs in subsection 1.1.1—10 (5)) or by subsection 1.1.1—10 (6)).

Attachment C – The five recommendations of the Ministers' report

Recommendation one:

That FSANZ develop and declare as urgent a proposal to amend the Code to prohibit the retail sale of pure and highly concentrated caffeine products.

Recommendation two:

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.

Recommendation three:

That a coordinated inter-agency consumer information campaign on the safety of caffeine consumption be developed and implemented in conjunction with the implementation of recommendation one, if adopted.

Recommendation four

That, prior to or in parallel with the consumer information campaign, guidance on the regulation of products containing pure or high concentrations of caffeine, and high caffeine content products, be developed by Implementation Subcommittee for Food Regulation (ISFR) for, and agreed by, enforcement agencies to inform compliance action.

Recommendation five

That targeted research on caffeine consumption across the Australian and New Zealand population, including consumption by specific vulnerable population groups, continue to be undertaken, including as part of the upcoming Intergenerational Health and Mental Health Study.

Attachment D – Declaration of urgency

For official use only

ATTACHMENT 1

COMMONWEALTH OF AUSTRALIA

FOOD STANDARDS AUSTRALIA NEW ZEALAND

FOOD STANDARDS AUSTRALIA NEW ZEALAND ACT 1991

DECLARATION OF URGENCY

I, Jenny Hazelton, an authorised Delegate for the purposes of section 95 of the Food Standards Australia New Zealand Act 1991 (the FSANZ Act), hereby declare under paragraph 95(1)(b) of the FSANZ Act that, in order to protect public health and safety, **Proposal P1054 – Pure and highly concentrated caffeine products** is an urgent proposal for the purposes of Part 3, Division 4 of the FSANZ Act.

JENNY HAZELTON
Acting General Manager
Risk Management and Intelligence Branch
[Position Number NZ008]

20 September 2019

Attachment E – Summary of submissions

Key Theme	*Submitter*	*FSANZ Response*
Issues around interpretation of the approved variation		
The approved variation may have provided a broad permission to add caffeine to all foods up to a limit of 1% or 5%.	VIC Dept. of Health and Human Services Department of Health Western Australia South Australia Health	The amendments made by the approved variation are expressly stated in the CFS and final consideration to be a prohibition and do not create or constitute a permission to add caffeine to all foods up to a limit of 1% or 5%. The issue appears to be based on a view that, prior to the approved amendment taking effect, the Code prohibited the addition of caffeine to any and all food or the presence of caffeine in any and all food. Independent expert advice provided to FSANZ indicated the Code did not impose such a prohibition. The Final Consideration Report and CFS report explained that the absence of a stated requirement in the Code, does not and cannot of itself constitute a prohibition. In the absence of an express prohibition on the addition or the presence of caffeine in any and all food, the amendments made by the approved variation cannot and do not constitute a permission to add caffeine to all foods up to a limit of 1% or 5%.
The approved variation does not stop food manufacturers: • adding caffeine to any and all foods (apart from cola drinks/ Formulated Caffeinated Beverages (FCBs), which are already provided for in the Code). • adding up to 4.9% caffeine to any solid or 'semi-solid' food which would encompass gel-like substances, nor adding up to 0.9% of caffeine to food that is a liquid food.	Telethon Kids Institute	See above response
The approved variation has inadvertently permitted the use of caffeine in food when not used as a food additive (e.g. as a stimulant). The approved variation has made the food additive standard permissions ineffective. A consequence of P1054 is that any food	VIC Dept. of Health and Human Services South Australia Health	The concern appears to be based on an assumption that, both before and after the approved variation took effect, because the Code permitted the use of caffeine as a food additive (i.e., in cola drinks), the Code prohibited its use in food for any other purpose unless that other use was expressly permitted by the Code. Independent expert advice to FSANZ indicates the Code imposes no such prohibition. Nor did it impose such a prohibition before the approved variation took effect.

Key Theme	Submitter	FSANZ Response
additive when not used to perform a technological function can be added at any level in any food. A manufacturer could decide that it was adding a food additive for reasons other than a Schedule 14 function, without limitation. The food additive standard now fails to operate as it was intended to work. The P1025 Code Revision does not limit the addition of food additives and substances to foods for technological purposes not listed in Schedule 14. This has resulted in an interpretation of permission, such that if caffeine is used as something other than a food additive, like a 'stimulant', then it would be permissible in a food, in an unspecified concentration. The intention of the Code has always been to restrict caffeine in the food supply, with express caffeine permissions only existing for FCBs (Standard 2.6.4) and cola beverages, when used as a food additive. There is no restriction on food where caffeine is present naturally.	Department of Health Western Australia	Prior to the revision of the Code in 2015, clause 2 of the then Standard 1.3.1 imposed a general prohibition on the addition of a 'food additive'. The term 'food additive' was not defined in the then Code itself. However, the Purpose section of the then Standard 1.3.1 stated what constituted a 'food additive' for the purposes of that Standard at that time. That is - A food additive is any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5. It or its by-products may remain in the food (emphasis added). This statement or definition is similar to the Code's current definition of what constitutes a food additive or use as a food additive. That is, addition to food for a prescribed and specific technological function. This position was recognised by the NSW Supreme Court in 2008, which stated that - This definition of "food additive" (which is to be found, not in the interpretation clause, but in the "Purpose" statement) is, to a point, a repetition of the definition of "nutritive substance" with the exception of the recognised purpose of the addition of the substance. … A "food additive" is a substance (having the same (negative) characteristics) which is added to achieve a "technological function". Schedule 5 of St 1.3.1 identifies the technological functions that are performed by food additives.[1] [emphasis added]. The above was discussed with stakeholders in the published P1025 Calls for Submissions and Approval Report on the revised Code - which all jurisdictions through the Forum endorsed. For example, as stated at page 45 of the P1025 Approval Report - The current Code only purports to regulate food additives that are added for the purposes, described as functions, listed in Schedule 5 of Standard 1.3.1. *A substance that is added to achieve a purpose that is not listed in Schedule 14 is not being used as a food additive*. …. It is beyond the scope of P1025 to expand the list of purposes for which a food additive might be used**.** [emphasis added]. This policy position has been on the public record since 2015.

[1] Tumney (NSW Food Authority) v Nutricia Australia Pty Ltd; Tumney (NSW Food Authority) v Michael Speare Hocken Sharpe; Tumney (NSW Food Authority) v Toni Lee Brendish [2008] NSWSC 1382 (22 December 2008), at para 27.

Key Theme	Submitter	FSANZ Response
		FSANZ notes that P1054 was an urgent response to address an immediate risk to public health and safety**.** It was beyond the scope of P1054 to expand the list of purposes for which a food additive might be used or to prohibit substances permitted for use as a food additive from being added to food for any other purpose. FSANZ also notes that any such amendments to the Code would first have to be found to be warranted by an evidence-based assessment that had due regard to each of the statutory assessment criteria required by the FSANZ Act. FSANZ also notes that an assessment of whether to prohibit the use of permitted food additives for other purposes would involve identifying each and every relevant food currently on the Australian and New Zealand market that currently contain any one of the over 300 permitted food additives at any level, after being added or used other than as a food additive purpose. It would then need to determine whether that use and that level should be permitted by the Code or not. This is impractical in the context of P1054. The intent of P1054 was to act – as requested by Ministers – within tight a statutory time frame to address an immediate and acute risk to consumers posed by pure and highly caffeinated products. To do so required FSANZ to work within the current requirements of the FSANZ Act and Code.
FSANZ had previously committed to addressing issues relating to food additives during Proposal P1025 Code Revision. This appears to have been put on hold. There is a need to expedite a review of the food additives standard (Standard 1.3.1) and the definitions of technological purpose.	VIC Dept. of Health and Human Services Department of Health Western Australia	A review of Code provisions relating to food additives was outside the scope of P1054 FSANZ has undertaken preliminary scoping for a possible review of the Code provisions relating to food additives, with input from the jurisdictions. However, FSANZ cannot consider commencing such a review without further detailed consideration of its scope, development of a clear problem statement and an examination of resourcing requirements. See also FSANZ's response above in relation to food additives and the Code's regulation of the latter both prior to P1025 and prior to the approved variation taking effect.

Key Theme	Submitter	FSANZ Response
The approved variation is inconsistent with the Ministerial Policy Guidelines for the Regulatory Management of Caffeine in the Food Supply.	VIC Dept. of Health and Human Services Department of Health Western Australia	FSANZ had regard to the Ministerial Policy Guideline for the Regulatory Management of Caffeine in the Food Supply in its assessment and in its review of the draft variation. See section 2.4.3 of this report. FSANZ must act in accordance with the FSANZ Act and Australian administrative law when developing standards. The FSANZ Act requires FSANZ - in its assessment - to have regard to the Ministerial Policy Guideline for the Regulatory Management of Caffeine in the Food Supply. However, the Act makes clear that the Ministerial Policy Guideline is not binding on FSANZ. The Guideline remains only one factor, among many others, that FSANZ is required to consider and weigh when deciding whether and how to amend the Code (See section 59 and paragraph 18(2)(e) of the FSANZ Act). The Guideline does not and cannot prevent FSANZ exercising the independent statutory discretion conferred on FSANZ by the FSANZ Act. Nor can the Guideline constrain FSANZ to reach a particular decision or prevent FSANZ taking all relevant considerations into account.
Issues related to safety		
The 1% and 5% limit is set too high and may not protect public health and safety – particularly if the limit results in an increase in the amount and variety of products containing caffeine.	VIC Dept. of Health and Human Services Department of Health Western Australia	An updated risk assessment of acute exposure to caffeine under the assessment of the variation re-confirmed that maximum concentration limits established in pure and highly concentrated caffeine solid and semi-solid foods and lower limits in liquid products were appropriate to address the acute health risk for Australian and New Zealand consumers from pure and highly concentrated caffeine products. The variation itself cannot 'increase in the amount and variety of products containing caffeine'. The Final Consideration Report, Call for Submissions and this report indicates the variation imposed a prohibition and does not create or constitute a permission. See responses above.
The variation allowing caffeine to be present at up to 5% in food for retail sale, and 1% in liquid food may still pose a risk to health of the general population, particularly for vulnerable population groups, including children, adolescents, pregnant and lactating woman and caffeine sensitive consumers.	Department of Health Western Australia	The focus of P10154 is the immediate and acute risk to consumers posed by pure and highly caffeinated products. For the reasons stated in the Final Consideration Report, in the Call for Submissions and in this report, FSANZ considers the approved variation to be the appropriate response to that specific risk. The new proposal provides an opportunity to consider whether additional risk management measures may be warranted for other types of foods containing caffeine, in order to protect consumers of these foods.

Key Theme	Submitter	FSANZ Response
The draft variation does not take into account the type of food and the manner in which the food is intended to be consumed. The Code is also silent on the reasonable amount of caffeine in single serving size. It would be easier to consume a higher volume of liquids containing up to 1% caffeine, than a food, such as dried instant coffee and tea. A pre-made beverage with caffeine present at a concentration of up to 1%, may be consumable as one serve. This would potentially mean an individual could consume a single serve of a caffeinated product and exceed what the EFSA deems to be the maximum reasonable amount of caffeine to consume in single serve, for an adult.		
It is a concern that a food may contain a caffeine concentration of up to 5% in solid and semi solid food, and up to 1% in liquid food, without being required to provide an advisory statement on the label. FCBs (Standard 2.6.4) containing a maximum 0.032% caffeine are required to have a caffeine advisory statement on the label, yet food and beverages with a concentration of caffeine up to 1% are not required to carry an advisory statement.	Department of Health Western Australia	The approved variation was a food regulatory measure specifically intended to address the immediate and acute toxicity risk from pure and highly concentrated caffeine products. FSANZ's assessment remains that mandatory labelling measures such as caffeine advisory statements are unlikely to be effective in terms of protecting consumers in relation to that specific risk and these specific types of products. See section 3.2.2 of the Final Consideration Report. The new proposal will provide an opportunity to consider whether additional risk management measures – such as labelling - for other types of foods containing caffeine may be warranted.
It is a concern that there is no requirement to declare how much caffeine is present in the food product for retail sale. Therefore, how does a caffeine sensitive individual or even a general adult	Department of Health Western Australia	See response above.

Key Theme	Submitter	FSANZ Response
consumer gauge how much caffeine they have consumed in a serve, or per one day quantity.		
It is a concern that aiming restrictions of high level caffeine products only at the retail (outlet) level, may not address the issue of pure and high caffeinated products being in the marketplace entirely. It is still not clear as to how consumers are sourcing/purchasing these concentrated form of caffeine powder/products i.e. who is purchasing them and from where (online for personal consumption and/or shared: or at retail and stacking with other foods containing caffeine; business purchase and resale online or as part of “health advice”).	Department of Health Western Australia	FSANZ considers the approved variation to be the appropriate response to the immediate and acute risk to consumers from pure and highly concentrated caffeine products. FSANZ understands that the marketing practices in question - such as stacking (i.e. selling multiple products with complementary attributes as one purchase) - generally occur in relation to sports foods. See in this regard, the action taken by the TGA in relation to such foods. The new proposal provides an opportunity to consider whether additional risk management measures may be warranted.
The revised maximum concentration limit for all foods should be 2%. Caffeine supplementation for sports should be conducted under the guidance of an Accredited Sports Dietitian. Notes that caffeinated sports foods (including strips, gels and chewables) will be formally addressed in the review of Standard 2.9.4, and looks forward to the outcomes of that review.	Sports Dietitians Australia	The approved variation prohibits a food for sale being a (non-liquid) food in which caffeine is present at a concentration of 5% or more. This is consistent with the updated risk assessment which confirmed that this limit was appropriate to address the acute health risk for consumers from pure and highly concentrated caffeine products. A level at 2% would unnecessarily impact caffeine-containing products on the market, which are safe to consume. The regulation of caffeinated sports foods has been addressed in part by the section 7 declaration under the TG Act and will considered further in the new proposal (see above).
As a result there is now the potential for caffeine to be added to an increasing range of products, putting children, pregnant women and others at risk, especially if	Telethon Kids Institute	The focus of P1054 is the immediate and acute risk to consumers posed by pure and highly caffeinated products. For the reasons stated in the Final Consideration Report, in the Call for Submissions and again in this report, FSANZ considers the approved variation the appropriate response to that specific threat.

Key Theme	Submitter	FSANZ Response
consumed along with more traditional caffeine products. FCBs are still widely available and accessible to young consumers (< 18 years) and pose an unacceptable risk to the health and safety of this vulnerable population group. The Code should therefore be amended so that • The changes made by the approved variation only apply to caffeinated powders / liquids / gels / semi-solid foods which require reconstitution or dilution by the consumer. • All other 'ready to consume' caffeinated foods and beverages should be prohibited to people under the age of 18 years in Australia and New Zealand, due to the significant negative impact these drinks have on children's health. • There is a maximum permitted caffeine amount per serve or a decree on certain products which should not contain caffeine		The amendments made by the approved variation apply to foods which require reconstitution or dilution by the consumer and to 'ready to consume' caffeinated foods and beverages. Cola-type drinks currently have specific permissions in the Code, which were in place prior to P1054. The new proposal provides the opportunity to consider whether additional risk management measures for foods containing caffeine and to protect the consumers of these food may be warranted.
Pure caffeine should not be sold as a retail product. Other caffeine addition, including energy drinks, should be treated like dietary supplements and be measured and regulated in dose per serve. There should be a recommended daily limit on the amount of caffeine consumed and that made clear on the packaging unit.	Individual (NZ)	The approved variation prohibits the retail sale of pure and highly concentrated caffeine products. That is, of foods in which total caffeine is present in a concentration of 5% or more (if the food is a solid or semi-solid food) or 1% or more (if the food is a liquid food). The new proposal provides the opportunity to consider whether additional risk management measures for foods containing caffeine and to protect the consumers of these food may be warranted.

Key Theme	Submitter	FSANZ Response
Specific Industry issues		
The current variation means Revvies Energy Strips may not be able to be sold as they contain a concentration of more than 5% caffeine, whilst only containing less than 0.04g of caffeine, equivalent to less than half the amount of caffeine than in a cup of instant coffee. Furthermore, an entire pack of five strips is consumed per day, this equates to only 200mg per day. This is half the 400mg amount recommended by FSANZ and still leaves room for other caffeine sources to be consumed. It seems inconsistent and it is not clear to us why Revvies Energy Strips are potentially being prevented from sale when they align with FSANZ's recommendations as to reasonable and safe caffeine consumption.	Revvies Energy Strips Ltd (late comment)	The regulation of products such as Revvies will be considered further in the new proposal.
General Industry issues		
Food manufacturers may not necessarily have the skills or knowledge to use highly concentrated caffeine ingredients in a safe and suitable way.	Department of Health Western Australia	Food manufacturers are required by Australian and New Zealand food and other laws (e.g. criminal) to manufacture safe food and to manage hazardous ingredients in a safe way. For these reasons, the onus is on food manufacturers to ensure that they have the requisite skills and knowledge as well as a risk management plan or other risk-based procedures for handling pure and highly concentrated caffeine ingredients.
The AFGC does not welcome a further proposal addressing limits to caffeine in food until *after* the implementation of a public consumer information campaign on safe caffeine consumption and, the continued monitoring of caffeine consumption	The Australian Food and Grocery Council (AFCG)	Recommendation three of the Ministers' report indicated that a coordinated inter-agency consumer information campaign on safe caffeine consumption be developed and implemented in conjunction with the implementation of recommendation one, if adopted. Although the second recommendation has guided FSANZ on the scope of the new proposal, elements of recommendation three may also be considered.

Key Theme	Submitter	FSANZ Response
through targeted research across Australia and New Zealand (and, then only if it clearly indicates that intake is a concerning issue among sub-populations at risk of over-consumption).		
General Enforcement issues		
An alternative approach is to amend Standard 1.1.1 – 10 (6) which states 'Unless expressly permitted by this Code, food for sale must not have as an ingredient or a component, any of the following: (j) raw apricot kernels;' (k) insert 'caffeine' here This would mean that caffeine, unless expressly permitted in the Code, could not be added to food. The amendments made by the approved variation can be repealed if the Code is amended to • prohibit the addition of caffeine to foods unless expressly permitted, and • set maximum compositional limits set where permitted (e.g. for cola drinks and formulated caffeinated beverages).	VIC Dept. of Health and Human Services Department of Health Western Australia South Australia Health	The scope of P1054 was the acute and immediate risk of pure and highly concentrated products only. The proposed alternative approach deals with caffeine generally in the food supply and was out of scope. Any variation to prohibit the presence of caffeine as an ingredient or a component in a general food for sale unless expressly permitted would therefore need to be justified. Such an amendment would need to conclude that the prohibition of caffeine at any level for any use or any purpose in any food was justified – other than where permitted by the Code. The assessment would also need to identify each and every food currently on the Australian and New Zealand market that contains caffeine at any level for any use or purpose and then determine whether each and every such food should be permitted by the Code or not.
Caffeine as a food can and could have been regulated by the Code as a novel food with limits on its use.	South Australia Health	Noted. The issues with reliance on novel food provisions of the Code to regulate caffeine were explained in the Review Report, the Final Consideration Report and the Call for Submissions. These reports discuss that to the extent that pure and highly concentrated caffeine products are novel foods for the purposes of the Code, their retail sale as a food and their presence as an ingredient or component in a food for retail sale would be prohibited by the Code and State and Territory food laws. The status of pure and highly concentrated caffeine products as a novel food remains untested by food regulators and the courts.

Key Theme	Submitter	FSANZ Response
There is no evidence provided that the amendment of Proposal P1054 is effectively regulating the use of caffeine as a food to prevent the caffeine poisoning case that prompted the development of the regulation in the first place.	South Australia Health	No evidence was provided to support the assertion that the amendment has failed or is failing to prevent poisoning by pure and highly caffeinated products – that is, by foods in which caffeine is present in a concentration of 5% or more (if the food is a solid or semi-solid food) or 1% or more (if the food is a liquid food), and which the approved amendment prohibited from retail sale. In contrast, reports to FSANZ staff are that retail outlets removed pure and highly caffeinated retail products from their shelves and from retail sale as a direct result of P1054 and the approved variation.
SA Health suggests option 2 together with option 3 should be considered. Do not reaffirm the amendment to standard 1.1.1–10(5), noting that this would not remove the approved variation until a separate proposal was prepared by FSANZ and the approved variation was repealed following repeal, the Code would continue to operate as it did before the P1054 urgent measure was put in place.	South Australia	For the reasons stated in this report, FSANZ has decided to prepare a proposal (Option 3). In terms of how the Code operated before the approved variation came into effect, see FSANZ's responses above.
New caffeinated products (an example of a certain brand of chocolates sold on-line was given) will begin to enter the Australian food supply, some of which may be desirable to children.	Department of Health Western Australia	The amendments made by the approved variation provide that a food for retail sale in Australia and in New Zealand cannot be a pure and highly concentrated caffeine product (as defined by that amendment). These and other 'new caffeinated products' are not entering or able to enter the Australian food supply because of the amendments made to the Code by the approved variation. See responses above. The new proposal provides the opportunity to consider whether additional risk management measures for foods containing caffeine and to protect the consumers of these food may be warranted.
A percentage limit of caffeine in food is difficult to enforce. An MPL means the maximum permitted level,	South Australia Health	Percentage (%) measurement and limits are consistently used throughout the Code. FSANZ is not aware of evidence to date of an inability to enforce these measurements and limits.

Key Theme	Submitter	FSANZ Response
measured (unless otherwise indicated) in mg/kg is more appropriate and consistent with the Code. Consideration should be given to removal of the percentage limits on caffeine to address the regulatory ambiguities they create.	VIC Dept. of Health and Human Services	If required, this issue can be considered further in the new proposal.
Under the Trans-Tasman Mutual Recognition Agreement (TTMRA), foods containing caffeine that comply with NZ laws may be sold in Australia and that certain sports foods and caffeine shots seem to be in the Australian marketplace through this mechanism.	Department of Health Western Australia	The administration and operation of the TTMRA is a matter for Government and not FSANZ. FSANZ understands that the *New Zealand Supplemented Food Standard* now adopts the P1054 variation and that, if so, products prohibited by the approved variation are not eligible for consideration under the TTMRA. Please refer to the submission received from New Zealand Food Safety. Under TGA's section 7, sports foods declared to be therapeutic goods are not eligible to be imported into Australia under the TTMRA.
The August 2013 Policy Options Paper on the Regulation of Caffeine in Foods issued by the Food Regulation Standing Committee states that the Code is silent on whether or not caffeine can be present in 'Formulated Supplemented Sports Food' (Standards 2.9.4).	Department of Health Western Australia	The regulation of caffeinated sports foods has been addressed in part by the section 7 declaration under the TG Act and will be considered further in the new proposal (see above). Formulated Supplemented Sports Foods (Standard 2.9.4) are currently being considered under P1010 and therefore were out of scope for P1054.
Issues relating to the food/medicine interface		
There is a lack of clarity for caffeine products due to the food-medicine interface. There is a need for a consistent approach to the regulation of products containing caffeine as foods and as therapeutic goods. The current two-pronged approach 'results in different	Complementary Medicines Australia	The operation of and interaction between the legislation regulating food and therapeutic goods was covered in the Final Consideration Report and in the Call for Submissions. The need for a two pronged approach to regulation of food and therapeutic goods is in the first instance a direct result of that legislation. That legislation also dictates to a large extent when and how public consultation occurs and what, when and how formulation, labelling and other requirements can be imposed on a food or on a therapeutic good. The administration and amendment of that legislation is a matter for Government and not FSANZ.

Key Theme	Submitter	FSANZ Response
and illogical approaches' (e.g. in consultation with stakeholders and in formulation and labelling requirements) and 'confusing information for industry and consumers on a number of products which from a consumer's view may be virtually indistinguishable'.		The regulation of therapeutic goods also remains a matter for the TGA and not FSANZ. As covered in the Final Consideration Report and in the CFS, given the operation and interaction between the two different legislative regimes, FSANZ and the TGA agreed on a two-pronged coordinated approach. Moving towards managing caffeine as both a food via the Code and as a therapeutic good via the TG Act was the most pragmatic response to the immediate and acute risk to consumers posed by pure and highly caffeinated products. Public consultation must occur as part of the new proposal. This provides opportunities for stakeholders to raise issues that they may have with Code requirements relevant to the proposal.
The amendments are no longer needed because of the actions taken by the TGA to address the risks from pure and highly concentrated caffeine products that are not foods. The amendments made by Proposal P1054 are no longer needed because the TGA therapeutic and poisons regulations are in place.	South Australia Health	The amendments made to the Code by the approved variation apply in the food supply in New Zealand and in Australia. The measures put in place by the TGA do not apply to the New Zealand food supply. FSANZ notes that the limits and exemptions provided under the TG Act, the section 7 declaration and the Poisons Standard. The new proposal provides an opportunity to consider whether the measures taken by the TGA do in fact cover the field in terms of all pure and highly caffeinated food in the Australian food supply.
The regulatory changes made by the TGA and the approved variation's changes to the Code are not consistent. This may prompt manufacturers to identify powders as a food, rather than a therapeutic, to enable them to add more caffeine.	VIC Dept. of Health and Human Services	What is considered 'a food' for Code purposes is determined primarily by the FSANZ Act and by the TG Act and not by FSANZ. See, for example, section 5 of the FSANZ Act.
FSANZ must clearly describe when a caffeinated product is considered a food. Pure caffeine and highly concentrated caffeine products should not be considered a food under the Code. These are therapeutic substances and are captured under the Therapeutic Goods	Department of Health Western Australia	See above responses.

Key Theme	Submitter	FSANZ Response
Act 1989. Pure and highly concentrated caffeine should be regulated as a scheduled poison by TGA.		
Supporting comments		
The AFGC supports the current permissions in the Code relating to the use of caffeine as an ingredient in formulated caffeinated beverages and, as a food additive in cola beverages. The AFGC Supports Option 1 (reaffirm the approved variation) and an education campaign for some sub-populations through the raising of another proposal for this purpose. The AFGC supports non-regulatory measures be undertaken first, such as a public consumer information campaign on safe caffeine consumption and targeted research of caffeine consumption across Australia and New Zealand as this will likely be relevant to the review of sports foods (P1010).	The Australian Food and Grocery Council	The current approved variation remains in place until the completion of the new proposal. For the reasons stated in this report, FSANZ has decided to prepare a new proposal, which will consider caffeine in sports food and whether a maximum limit on caffeine for foods in the general food supply. It will also consider the extent of the risk posed to sensitive subpopulations and whether and how any such risk should best managed. An education campaign may be an output of the new proposal.
Supports option 3 and recommends that further consideration needs to be given to the form and presentation of caffeine-containing foods.	New Zealand Food Safety	Noted.
The consultation document correctly points out that paragraph 1.1.1—10(5)(g) in the Australia New Zealand Food Standards Code, will apply to supplemented foods under the *New Zealand Food*	New Zealand Food Safety	Noted

Key Theme	Submitter	FSANZ Response
(Supplemented Food) Standard 2016.		
Supports the inclusion of the variation to the Code to limit caffeine in foods (solid and semi-solids) to 5% (5g/100g) and in liquids to 1% (1g/100mL).	Australian Beverages Council Limited The New Zealand Beverage Corporation	Noted.
Supports the existing permissions in the Code relating to the use of caffeine as an ingredient in formulated caffeinated beverages (Standard 2.6.4) and as a food additive in cola beverages (Schedule 15).	The New Zealand Beverage Corporation	Noted.
In support of Option 3, to prepare a proposal to amend and/or add to the approved variation that would consider the risk posed by caffeine in the wider food supply to sensitive subpopulations. Supports the proposal to clarify the permissions of the Code for caffeine when added to a food as an ingredient other than a 'food additive' as defined by Schedule 14 or as a stimulant in formulated caffeinated beverages. Notes and supports the current proposal P1010 to review Standard 2.9.4 and caffeine in sports supplements.	Department of Agriculture, Water and the Environment	Noted.
NSW welcomes FSANZ's commitment to prepare a new proposal that considers the risk posed by caffeine in the wider to provide the community, industry and	The NSW Food Authority	Noted.

Key Theme	Submitter	FSANZ Response
regulators with certainty on the use of caffeine in foods.		

Attachment F – Summary of suggested regulatory reforms relating to caffeine

VIC Dept. of Health and Human Services

Suggested the following reforms.

- Address the ambiguity in Code permissions for the addition of caffeine to food, namely the prescriptive approach for two products (cola and formulated caffeinated beverages) but the simultaneous interpretation that caffeine can be added for other purposes to a broad range of foods up to 1% or 5%, depending on the form of the food.

- Prohibit the addition of caffeine to food unless expressly permitted. The Code should not prescribe limits for naturally occurring caffeine in food, for example teas, coffee and chocolate. Permissions for caffeine to be added to new products should then be considered on a case by case basis and should consider the risk to the broader population, including sensitive groups.

- Reconsider need for broad maximum limits for caffeine in food. Permissions for foods to contain added caffeine already include maximum limits, making these broad limits redundant.

- Expedite a review of the food additives standard (Standard 1.3.1)

South Australia Health

A new proposal being raised by FSANZ to regulate caffeine more broadly in food is supported (Option 3)

Suggested the following reforms

- Prohibit the addition of caffeine to foods unless expressly permitted

- Set maximum compositional limits set where permitted (e.g. for cola drinks and formulated caffeinated beverages).

- Repeal the maximum limits for caffeine introduced by P1054

- If there is concern that caffeine is being sold at retail as a single ingredient, then the food additives standard should be amended to restrict the retail sale of caffeine by adding a condition. Alternatively, caffeine as a food could be given permission as a novel food with limits on its use. Both these suggested ways of amending the Code would provide an express permission for caffeine with a limit or condition applied.

- Take action to provide pure and highly concentrated caffeine products are not ‘food’ regulated by the Code and the Food Acts

  The TGA is best placed to regulate these products. The limits introduced by the Therapeutic Goods Administration should address the risks from pure and highly

concentrated caffeine products that are not foods.

- The Food Acts of the States and territories will continue to prohibit the sale of a food that is not safe and suitable - including caffeine use as a food.

The Department of Health Western Australia

Preferred approach is to support Option 3: prepare a proposal to amend and/or add to the variation.

Suggested the following reforms

- Prohibit the addition of caffeine to foods unless expressly permitted. The permission to use caffeine as a food additive in kola-type beverages, and as an ingredient in FCBs, would still apply.

- A requirement for the concentration of caffeine in products to be declared on the food label, perhaps by way of addition of this information to the Nutrition Information Panel. This would enable consumers to make informed choice and manage any potential sensitivities to excessive caffeine consumption.

- Extent the requirement for FCB to carry a caffeine advisory statement to all products containing caffeine.

- Expedite a review of the food additives standard (Standard 1.3.1) and the definitions of technological purpose.

- Provide a permission for caffeine in formulated supplementary sports food to regulate the use of caffeine as a ‘stimulant’ in these kinds of products.

- Consider natural sources of caffeine in assessing dietary exposure and setting limits. Consider limits on the total amount of caffeine permissible in products containing botanicals like guarana or high caffeine coffee beans.

- Establish a maximum limit, in accordance with Standard 1.4.1 and Schedule 16, for caffeine in foods in a similar manner to that which exists for quinine (Schedule 19 – 6 - Maximum level of natural toxicants. In doing so, consider natural sources of caffeine when assessing dietary exposure and consider limits on the total amount of caffeine permissible in products containing botanicals like guarana or high caffeine coffee beans

Telethon Kids Institute

Suggested the following reforms

- Prohibit the sale of formulated caffeinated beverages to people under the age of 18 years
- Restrict the changes made by the approved variation only to caffeinated powders / liquids / gels / semi-solid foods which require reconstitution or dilution by the consumer.

- Prohibit the sale of all other ‘ready to consume’ caffeinated foods and beverages to people under the age of 18 years in Australia and New Zealand

- Set a maximum permitted caffeine amount per serve for certain products and ban all other foods from containing caffeine.