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Approval report – Proposal P1056 – Caffeine review

Supporting document 5 – Decision Regulation Impact Statement

Office of Impact Analysis ID OIA24-07750

Executive summary

Food Standards Australia New Zealand (FSANZ) has prepared and assessed a proposal to review permissions for caffeine in sports foods and in the general food supply and considered the risk caffeine poses to sensitive sub-populations.

This Decision Regulation Impact Statement (DRIS) has been developed and provided to decision makers to inform their decision to approve the proposed changes.

The DRIS contains the impact analysis (including the consideration of costs and benefits) of the proposed changes.

FSANZ expects the proposed changes to the Code will lead to an overall net benefit to consumers, businesses and governments.

This conclusion is discussed in more detail below.

What is the problem?

FSANZ has undertaken a safety assessment (Supporting document (SD) 1), dietary intake assessment (SD 2), social science literature review (SD 3) and an assessment of caffeine and sports performance (SD 4).

These assessments examined the risk posed by caffeine consumption in the general population and in various sub-populations, intakes of caffeine from foods, consumer understanding and behaviour regarding caffeine in both general foods and sports foods, and the effect of caffeine on aerobic exercise performance.

The Australia New Zealand Food Standards Code (the Code) already has some provisions that regulate caffeine in the food supply and protect vulnerable populations, which align with the above assessments.

However, FSANZ identified some areas of the Code which do not align with the assessments, including:

- there are no requirements specifically relating to caffeine when caffeine is present in Formulated Supplementary Sports Food (FSSF), as a result:
  - many FSSF on the market exceed the safe level of caffeine, or are likely to result in consumers exceeding the safe level (if other sources of dietary caffeine are considered)
  - information about the caffeine content of products is provided inconsistently, impacting on consumer ability to be informed about their caffeine intake
  - some caffeinated, ready-to-eat, FSSF on the market are sold in multi-serve packages which increase the risk of over consumption

- the Code does not prevent the addition of caffeine to general food, if there was a trend toward adding caffeine to more foods, the risks of consumers exceeding the recommended maximum safe recommended limits of caffeine would increase
- some coffee beverages (e.g. coffee milks) on the market contain more than the safe level of caffeine per serve, with no requirement to provide information to consumers.

Why is government action needed?

Government action is needed to update the Code to address the problems identified above. This action is needed to:

- address risks to public health and safety
- improve the quality of information provided to consumers.

The Code has the capacity to manage these risks and ensure quality information is provided to consumers, as demonstrated by existing provisions of the Code (for example Standard 2.6.4 which regulates energy drinks).

In amending the Code, FSANZ objectives are to:

- minimise the risk of overconsumption of caffeine (especially for vulnerable people)
- provide regulation that enables the safe sale and consumption of sports foods that assist sports people in achieving specific performance goals
- provide adequate information to enable consumers to make an informed choice, and for governments to monitor the market and enforce the Code
- provide an effective regulatory framework within which the food industry can work efficiently.

What options have been considered?

FSANZ is considering two options:

- Option 1 – status quo (no change)
- Option 2 – regulatory option – a series of amendments to the Code.

Option 2 includes the following changes to the Code:

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

What is the likely net benefit of each option?

There would be no change to the Code under Option 1, and by definition there would be no regulatory impacts.

FSANZ's view is that Option 2 has a net benefit, the benefits of the proposal outweigh the costs.

The costs and benefits of the proposal are summarised in the table below. The table below presents impacts on a society wide perspective. Therefore, quantified costs may be experienced by industry or passed on partially or fully to consumers.

Table: summary of costs and benefits for Option 2, by quantified or unquantified

Costs	**Quantified**	Reformulating FSSF with more than 200 mg per serve – $A1.4m to $2.7m
		Relabelling FSSF to add required elements or update post reformulation – $A1.9m to $3.8m
		Relabelling coffee containing drinks with more than 200 mg per serve of caffeine – $A0.1m
		Total quantified costs – $A3.4m to $6.6m
	Unquantified	Reformulating general foods with added caffeine, guarana extract
		Withdrawal of product varieties or lines
		Repackaging impacted FSSF
Benefits	**Unquantified**	Health benefits from reduced risk of caffeine overconsumption
		Potential improvements in healthcare spending efficiency
		Improved quality of information for consumers
		Improved enforceability and regulatory certainty

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

However, almost all costs for FSSF have been quantified, which are the most significant costs for the proposal overall. This enables a break-even analysis to be calculated for the FSSF related aspects of the proposal. As the costs for relabelling coffee containing drinks were also quantified, these costs have been included in the break-even analysis.

The break-even analysis shows that consumers, government and/or industry will need to receive benefit at the amount of $0.26 to $0.52 per year per daily user[1] of caffeinated FSSF (5.3% of adult population in Aus and NZ) for the benefits of the proposal to exceed the quantified costs.

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

FSANZ considers it likely that this benefit will be achieved, primarily through small reductions in sleep disturbances, higher blood pressure and anxiety.

Who was consulted and how was their feedback incorporated?

FSANZ conducted three public consultation rounds in December 2022, March 2025 and October 2025.

The objectives of consulting with stakeholders include receiving feedback on:

- FSANZ's summary of the evidence, for this proposal this includes the:
  - safety assessment (SD 1)
  - dietary exposure assessment (SD 2)
  - social science literature review (SD 3)
  - assessment of caffeine and sports performance (SD 4)
- proposed risk management approaches, including whether:
  - stakeholders agree with the approach
  - the approach achieves its intended objectives
  - there are any unintended effects of the approach
- draft amendments to the Code, including comments on whether the amendments
  - achieve the risk management approach
  - are clear (to businesses) and enforceable (by governments)
- assessments of costs and benefits.

FSANZ considered all comments. In a number of cases FSANZ changed its proposed approach.

Where changes were not made, FSANZ provided explanations in subsequent consultation documents or the approval report.

What is the best option from those considered, and how will it be implemented?

FSANZ's view is that Option 2 is the best option to address the problem outlined above.

This is because Option 2 is likely to have a net benefit and achieves the desired outcomes of the proposal.

Maintaining status quo does not achieve the desired outcomes of the proposal. Primarily, it does not address the risks of overconsumption. It also doesn't resolve other problems identified.

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[1] A proportion of the additional label change costs arising from the amended proposal are likely to impact non-sports food consumers, which means that the break-even amount may be lower than estimated

Option 2 achieves the desired outcomes of the proposal. It does this by:

- prohibiting the sale of caffeine as a food and the addition of caffeine (and guarana extract) to food, unless permitted, minimising the risk of overconsumption of caffeine in the case of a trend toward greater caffeination of the food supply
- setting a limit for caffeine in FSSF that balances safety and performance goals
- establishing labelling requirements for FSSF and some coffee drinks, to provide consumers with clear and consistent information to make informed choices
- establishing packaging requirements for some FSSF to reduce the risk of inadvertent overconsumption.

The FSANZ Board will make a decision to approve, amend or reject the proposed variations to the Code, informed by this DRIS and other evidence in accordance with *Food Standards Australia New Zealand Act 1991*.

It is expected that this proposal will follow standard implementation procedures for changes to the Code.

How will the chosen option be evaluated?

Across Australia and New Zealand's food regulatory system, multiple agencies have responsibility for actively monitoring and evaluating food standards including FSANZ and other Commonwealth agencies and the jurisdictions.

Under the food regulatory system, the Commonwealth and jurisdictions develop the policy principles against which FSANZ consider when developing food standards. This structure also provides for reviewing the outcomes of the standards against their policy principles.

Table of contents

Glossary

Term	Description
Advisory statement	A statement that must be provided to alert consumers to the presence of a specific food or ingredient in a food, exact wording of the statement is not specified in the Code
CFS	Call for submissions
Code	Australia New Zealand Food Standards Code
DRIS	Decision regulation impact statement
FCB	Formulated Caffeinated Beverage, a product regulated under Standard 2.6.4 of the Food Standards Code. Commonly referred to as energy drinks.
FSANZ Act	*Food Standards Australia New Zealand Act 1991*
FSSF	Formulated Supplementary Sports Food, a product regulated under Standard 2.9.4 of the Food Standards Code
Guide	*Regulatory Impact Analysis Guide for Ministers' Meetings and National Standards Setting Bodies*
One-day quantity	The amount of FSSF which is to be consumed in one day in accordance with directions specified in the label
P1010	FSANZ proposal P1010 - Formulated supplementary sports foods
P1054	FSANZ proposal P1054 - Pure and highly concentrated caffeine products
SD	Supporting document to this proposal
SKU	Stock Keeping Unit - which are different pack sizes and flavours of the individual products
Warning statement	A statement that must be provided to alert people to a severe health risk posed by a food or ingredient, exact wording of the statement is specified in the Code

1 Introduction

Proposal P1056 – Caffeine review is considering amending the Australia New Zealand Food Standards Code (the Code) to update the permissions for caffeine in Formulated Supplementary Sports Foods (FSSF) and in the general food supply.

This Decision Regulation Impact Statement (DRIS) contains the impact analysis (including the consideration of costs and benefits) FSANZ has undertaken on the proposed changes, which will be provided to decision makers.

The DRIS has been prepared to meet the requirements of:

- *Regulatory Impact Analysis Guide for Ministers' Meetings and National Standards Setting Bodies* of the Office of Impact Analysis (the Guide)(OIA 2023b)
- Section 59 of the *Food Standards Australia New Zealand Act* 1991 (FSANZ Act).

1.1 Assessment by the Office of Impact Analysis

This DRIS has been prepared in line with the Guide.

The Office of Impact Analysis (OIA) guidance requires FSANZ to answer the following impact analysis questions when developing a DRIS:

1. What is the policy problem?
2. Why is government action needed?
3. What are the objectives of government action?
4. What policy options are to be considered?
5. What is the likely net benefit of each option?
6. Who was consulted and how was their feedback incorporated?
7. What is the best option from those considered?
8. How will the chosen option be implemented and evaluated?

These questions have been answered in the sections that follow.

The OIA has assessed the DRIS as being compliant with the requirements (OIA 2023b) by the OIA. [2]

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

This DRIS is based on SD 5, and extended where possible based on:

- stakeholder feedback, to both the 2nd CFS and an additional Consultation Paper released after the 2nd CFS
- FSANZ research projects, which have concluded since the 2nd CFS was published
- further analysis since the publishing of the 2nd CFS.

1.2 Consideration of costs and benefits

In assessing P1056 and in making its decision to prepare the amendments to the standards, FSANZ was also required by Section 59 of the FSANZ Act to have regard to whether the costs that would arise from the proposed measure outweigh its direct or indirect benefits.

[2] *Refer to the OIA website - https://oia.pmc.gov.au*

As above, FSANZ has decided to prepare a set of proposed amendments to the standards within the Code. This includes amendments to Standard 1.1.1 (general provisions), Standard 1.2.1 (requirements for labelling), Standard 2.10.4 (Miscellaneous standards for other foods) and Standard 2.9.4 (specific standard for formulated supplementary sports foods).

This decision reflects in part FSANZ's assessment that the costs that would arise from these proposed amendments will not outweigh the direct or indirect benefits of those proposed amendments. This DRIS sets out the reasons for that assessment, in section 5.3 below.

The assessment was based on the best available information at the time the decision was made to prepare the amendments. That included submissions received from stakeholders in response to the 1st and 2nd CFS and additional consultation paper.

1.3 Scope

The scope of the proposal includes:

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

1.4 Background

FSANZ concluded, based on the evidence reviewed for the assessment, that there was a need to create a new proposal to consider wider issues than those considered in P1054 (FSANZ 2020b). The issues were identified as:

- 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, and
- the need to consider a maximum limit on caffeine for foods in the general food supply, and FSSF (either through the new proposal, or the existing proposal P1010).

FSANZ decided to progress the consideration of a maximum limit on caffeine in FSSF in P1056, rather than through the existing FSSF proposal (P1010 – Formulated Supplementary Sports Foods).

As noted in the assessment report, the majority of stakeholders supported FSANZ's decision, against the other options which were to leave the amendments as is or completely remove them.

1.5 Current code requirements

The Code already has some provisions that regulate caffeine in the food supply and protect vulnerable populations. Some of these provisions apply to specific products while there are also some broad prohibitions on what can be sold as food or added to food.

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

Caffeine is permitted to be added to cola-type drinks (as a food additive - flavouring substance), up to a maximum permitted level (MPL) of 145 mg/kg.

For both energy drinks and cola beverages (and food containing cola beverages), caffeine is required to be listed in the statement of ingredients, and they must be labelled with a statement to the effect that they contain caffeine. This statement is also required to be provided on the label of any product that contains guarana.

Energy drinks are required to bear an advisory label that the product is not suitable for children, pregnant or lactating women, or individuals sensitive to caffeine, and the amount of caffeine must be quantified on the product's label.

P1054 (previously discussed in section 1.4) amended the Code so that 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 Code also has some general restrictions that apply to the use of caffeine in foods. For a substance (such as caffeine) to be used for the purposes as a food additive[3], processing aid[4] or nutritive substance[5] it must be listed as a permitted substance in the Code for those purposes. There is no permission for caffeine to be used as a nutritive substance or processing aid, and the only permission for caffeine as a food additive is for flavouring cola beverages (as noted above).

The Code also prohibits the sale of novel foods, or the use of novel foods as ingredients (unless they have been assessed by FSANZ and are listed in the Code). Novel foods are non-traditional foods that require assessment by FSANZ to establish their safety before they are added to the food supply[6]. Therefore, any food containing caffeine that is determined to be novel would be prohibited from sale or use as an ingredient.

1.6 Current requirement outside the Code

Some risk related to caffeinated sports foods in Australia is already managed by the *Therapeutic Goods Act 1989.*

As a starting point, if a food complies with the Code, it is not a therapeutic product in Australia. However, the Therapeutic Goods Administration (TGA) can declare Code compliant foods as a therapeutic under the *Declared Goods Order 2019*, where the following circumstances apply:

- the food is used, advertised or presented for supply to improve or maintain physical or mental performance in sport, exercise or other recreational activity and either:
  - it contains certain substances, including substances listed in the Poisons Standard, or
  - it is in the form of a tablet, capsule or pill (TGA 2025).

Caffeine is listed in the Poisons Standard if a product contains 600 mg or more per recommended dose. This means any product that would otherwise be a sports food that contains 600 mg of caffeine per serve would be declared as a therapeutic good by the TGA, and in effect is available by prescription only in Australia (TGA 2025).

In New Zealand, the *New Zealand Food (Supplemented Food) Standard 2016* (the Standard) permits caffeine to be added to a supplemented food (such as a sports food).[7] The Standard and Code operate alongside each other in New Zealand to regulate sports foods.

The amount of caffeine added is not restricted by a maximum limit under the Standard. The label must include an advisory statement to the effect that the food contains caffeine and is

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[3] *Food additives perform technological purposes in foods, such as being an anti-oxidant, colourant, or flavouring*

[4] *Processing aids perform technological purposes in the manufacturing process but not the final food, for example solvents used to decaffeinate coffee beans*

[5] *Nutritive substances are added to foods to achieve a nutritional purpose, i.e. some kind of nutritional benefit for the consumer*

[6] *For more information refer to the novel foods page on the FSANZ website*

[7] *New Zealand Supplemented Food Standard 2016*

not recommended for children, pregnant or lactating women, or individuals sensitive to caffeine, and the label must include the quantity of caffeine in the supplemented food. This labelling requirement does not apply where caffeine is added for a technological function only (e.g. using cocoa to add a chocolate flavour).

Products complying with the Standard may be imported to Australia under the Trans-Tasman Mutual Recognition Arrangement (TTMRA). The TTMRA allows any good that can legally be sold in New Zealand to be legally sold in an Australian jurisdiction, and vice versa, regardless of differences in regulatory requirements. However, the TTRMA doesn't apply to therapeutic goods and foods that have been risk categorised.

A full account of the existing regulation is provided at section 1.4 of the Approval Report.

1.7 Assessment for P1056

As part of FSANZ assessment of this proposal the following work was completed to identify risk and inform appropriate risk management options:

Safety assessment - A hazard assessment of caffeine (SD1) was conducted. This assessment included a systematic search for literature on the safety of caffeine, in addition to reports published by international regulatory agencies related to the safety of caffeine, a report published by FSANZ (FSANZ 2000), and available data from poisons centres. A limitation of the analysis was that some areas of interest were not studied in the literature, including a threshold for adverse effects in pregnant women.

Dietary intake assessment - A dietary intake assessment (SD2) was also conducted. This assessment followed FSANZ's well established methodology for assessing dietary intakes, using a model that combines representative food intake data from both Australia and New Zealand as well as comprehensive food composition data (FSANZ 2024b). A limitation of this analysis is the survey data were collected in 2011-12 (Australia) and 2008-09 (New Zealand), which may not reflect changes in the consumption of caffeinated food and beverages over the past 10 to 12 years. Given this limitation, FSANZ has also considered additional evidence in the social science literature review (see below). In addition, data was not available to directly assess the intake of caffeine for children under 2 and pregnant women.

Social science literature review assessment - A social science literature review (SD 3) was conducted to understand consumer behaviours, understandings, risk perceptions, and information sources regarding caffeinated foods. This was a rapid systematic review of available literature. A limitation of the review was that for some research questions, conclusions were based on just one or two studies, and most studies did not use nationally representative samples therefore the results were not generalisable to the whole population.

Assessment of caffeine and sports performance - FSANZ assessed evidence from human trials investigating the impact of caffeine intake on time trial performance in sports including cycling, running, rowing and swimming (SD4). Forty publications representing 39 studies and 42 pairwise comparisons were included.

1.8 Caffeine Consumption: Motivations, Risks, and Safe Intake Levels

1.8.1 Why do people consume caffeine?

Any risks and potential regulation of caffeine (outlined in the next sections) need to be considered in the context of how often it is consumed and what it is consumed for.

Caffeine has a long history of safe use and is widely consumed. Data from national nutrition surveys show that caffeine was consumed by 87% of Australian and 93% of New Zealand adults on day one of the surveys, with the major sources being coffee, tea, soft drinks, and chocolate (and other foods that contain these as an ingredient, for example cake) (SD2, section 3.4).

According to the social science literature review (SD3), reasons for consuming caffeinated food and beverage products include:

- Hedonic reasons like warmth, the taste or to relax (tea, chocolate, cola)
- Social reasons like meeting with family and friends (tea and coffee)
- Functional effects like energy (coffee and FSSF).

In addition to the above, in a focus group study of New Zealand consumers (Wham et al. 2017) the authors found:

- Coffee, pre-workout sports supplements, sports gels and caffeine tablets were used to improve athletic performance and endurance
- Sports supplements and caffeine tablets were perceived to be more suitable for competitive athletes
- Coffee and energy drinks were deemed more appropriate for recreational athletes.

Results of a FSANZ consumer insights survey have found consistent results to the above literature review in relation to FSSF (FSANZ 2025). Australian and New Zealand consumers were asked why they consumed different sports food products, while the reasons for consuming FSSF were highly variable, preparing for intense sport or exercise and maintain energy or hydration for intense sport or exercise were common reasons selected for products that are likely to be caffeinated (i.e. pre-workout products and energy gels, goos or gummies).

FSSF are regulated in the Code[8] as a special purpose food. Any product regulated as a sport food is defined in the Code as '*a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals*.'

While the focus of the standard is food for sports people or athletes, research from Australia and New Zealand suggests that FSSF consumption is also no longer limited to athletes. A 2013 FSANZ consumer survey found around 60% of Australian and of New Zealand supplementary foods users indicated that they last consumed the product in an exercise-related context[9] (FSANZ 2013). A 2023 FSANZ consumer insights survey found that less than half of respondents who indicated they regularly consume sports foods (47.73%) said they only used sports foods within a physical activity-related context (FSANZ 2024a).

Therefore, any update to the sports food standard via P1056 needs to ensure the safety of consumers whilst also considering the specific nutritional or performance goals.

To inform this proposal, FSANZ undertook a review of the evidence on whether caffeine has a beneficial effect on sports performance, and at what dose (SD4).

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[8] Regulated under Standard 2.9.4 – Formulated Supplementary Sports Foods

[9] Caution is required in interpreting this figure. Because the question only asked about when the person last used the product, respondents who last consumed the supplementary food outside of a sporting or exercise occasion may still be physically active.

The review concluded with a low level of certainty[10] that caffeine has a small beneficial effect on time trial performance after caffeine intake when compared to placebo. The dose level at which a small beneficial effect is observed lies within the range 1.25–3 and 6 mg of caffeine per kg of bodyweight.

FSANZ (in the 1st CFS) also reviewed the regulation of caffeine by international sporting bodies. Most relevant to the proposal is Australian Institute of Sport (AIS) Supplement Framework which classifies caffeine as a Group A substance, which means that the AIS has concluded that there is 'strong scientific evidence for use in specific situations in sport using evidence-based protocols' (AIS 2025). A similar conclusion was reached by the International Olympic Committee (Maughan et al. 2018).

1.8.2 What are the safety risks from consuming caffeine?

While caffeine has a long history of safe use, excess consumption of caffeine can have negative health consequences, the most serious being death.

FSANZ conducted a safety assessment of caffeine (SD1). The safety assessment identified that the consumption of caffeine, either from chronic (habitual) intake or through an acute (single) dose can have significant health impacts in some circumstances.

The following table summarises some of the potential acute negative effects of caffeine in adults identified by the safety assessment.

Table 1.1 – Negative health effects of caffeine in adults, by acute dose

Acute dose	Potential effect identified by studies	Source/ studies
100 mg	May delay sleep and reduce sleep duration	FSANZ (2000) EFSA (2015)
140 mg	Minor increase in diastolic pressure, a measure of blood pressure	FSANZ (2000)
200 to 250 mg	Increase in blood pressure Cardiovascular issues such as hypertension or a rapid heart rate (due to increase in plasma catecholamines) Anxiety and sleep disturbances (due to increase in plasma catecholamines) Reduction in myocardial blood flow when exercising	EFSA (2015)
400 to 500 mg	Increase in anxiety in psychologically normal subjects	EFSA (2015)
500 mg and above	Rate of clearance of caffeine is decreased, meaning caffeine stays in the body longer which results in greater risk to health	USFDA (2018)
1,200 mg	Rapid heart rate (tachycardia) Abnormal heart beats (ventricular arrhythmia)	FSANZ (2000) USFDA (2018)

[10] The level of certainty in the evidence was downgraded due to indirectness (time trial performance in athletes does not represent the general Australian and New Zealand populations), and risk of bias. For more information refer to SD4.

	Seizures	
3,000 mg	Lowest recorded dose that has led to death of an adult (that FSANZ has been able to identify)	FSANZ (2000)
5,000 to 10,000 mg	Life-threatening dose, typically due to cardiac arrest	FSANZ (2000)

1.8.3 What is the safe level of caffeine consumption?

Caffeine is a substance that has maximum safe daily intake levels. According to the safety assessment, these levels vary depending on bodyweight, age and sub-population group (SD1, section 2). The following table provides a summary.

Table 1.2 – Recommended safe level of caffeine consumption, by population sub-group

Group	Dose	Recommended safe level of consumption
Adults	Single dose	3mg of caffeine per kilo of bodyweight 210 mg for a 70kg person
	Daily total	5.7mg of caffeine per kilo of bodyweight 400 mg for a 70kg person
Children and adolescents	Single dose	Same as adults, adjusted for lower bodyweight
	Daily total	Same as adults, adjusted for lower bodyweight
Pregnant women	Single dose	No recommendation
	Daily total	≤ 200 mg

1.8.4 Are people consuming caffeine at safe levels?

Most people typically consume caffeine at safe levels.

Caffeine consumption is typically self-limiting, consumers generally learn to regulate their intake to achieve the beneficial effects of caffeine while avoiding the adverse effects (SD1, section 2.5). For example, when consuming products with naturally occurring caffeine (such as coffee and tea) any negative symptoms of caffeine intake will be experienced gradually, which typically will result in consumers stopping consumption before more serious negative effects are felt.

Evidence from the most recent national nutrition surveys (SD2, section 3.1) suggests that estimated usual caffeine intakes exceeded the recommended maximum level for the following population groups:

- 6% of Australian adults aged 20 years and above
- 2% of New Zealand adults aged 15 years and above

In addition, consumer studies show (SD3, research question 2):

- 0.8% to 15.6% of pregnant women exceed the recommended safe level
- 14% to 17% of adults may be regularly exceeding the daily recommended limit
- some sub-groups may be more likely to exceed the daily recommended limits, for example people who do shift work (up to 33%) and athletes.

After consideration of the evidence, FSANZ's risk assessment concluded that the sub-populations at potential risk include users of supplements and FSSF that are not accurately labelled, infants and pre-schoolers, athletes, and pregnant women (section 2.2, 2nd CFS).

2 What is the problem?

A comprehensive and rigorous review of the available evidence, outlined in the section 1.7 above, examined the risk posed by caffeine consumption in various sub-populations, intakes of caffeine from foods, consumer understanding and behaviour regarding caffeine in both general foods and FSSF and the effect of caffeine on aerobic exercise performance.

The Code already has some provisions that regulate caffeine in the food supply and protect vulnerable populations, which align with the above assessments.

However, FSANZ identified some areas of the Code which do not align with the assessments, including:

- there are no requirements specifically relating to caffeine when caffeine is present in FSSF, as a result:
  - many sports food products on the market exceed the safe level of caffeine, or are likely to result in consumers exceeding the safe level (if other sources of caffeine are considered)
  - information about the caffeine content of products is provided inconsistently, impacting on consumers ability to be informed about their caffeine intake
  - some caffeinated, ready-to-eat, FSSF on the market are sold in multi-serve packages which increase the risk of over consumption
- the Code does not prevent the addition of caffeine to general food, if there was a trend toward adding caffeine to more foods the risks of consumers exceeding the recommended maximum limits of caffeine would increase
- some coffee beverages (e.g. coffee milks) on the market contain more than the safe level of caffeine per serve, with no requirement to provide information to consumers.

The following sections explain the findings in more detail.

2.1 Regulatory gaps – caffeine in FSSF

The purpose of the proposal was to identify whether additional measures are required to protect public health and safety.

FSANZ found that additional measures are required for FSSF. At present, the Code does not prohibit the addition of caffeine to FSSF. This means that there are no requirements specifically relating to caffeine when caffeine is present in FSSF (e.g. labelling requirements).

As noted above, in New Zealand the Code and the New Zealand Food (Supplemented Food) Standard 2016 regulate FSSF, resulting in some products sold in Australia and New Zealand being outside the scope of the Code.

Chapple et al., 2024 reports that, over the past decade, a vast range of new products, available in mainstream retail settings (e.g., supermarkets) (Chapple et al., 2023) has developed, alongside an increase of 152% in retail sales in Australia (Euromonitor International, 2023a) and similar trends are seen throughout the world (Euromonitor International, 2023b).

Many FSSF on the market that contain caffeine and are widely available. The most common example of caffeinated FSSF are pre-workout products, which are intended to be taken to increase energy when performing exercise.

FSSF are being increasingly consumed in the community. Euromonitor (2024a, 2024b) estimate that sales of non-protein sports nutrition products[11] have a compound annual growth rate (for the 6 years to 2024) of:

- 9.4% in Australia
- 6.5% in New Zealand.

Caffeine is often present at high concentrations in FSSF. A scan of products on the market found a number exceed 200 mg per serve, the recommended safe level.[12] There are no specific requirements in the Code to prevent these products containing more than the safe level (except for the concentration limits noted previously).

In addition, the way some FSSF are sold means they may be higher risk than other caffeinated foods. Some FSSF are sold in small volume ready to eat portions such as gummies or strips, which makes them easier to consume during sports. Due to their size, these products can be easily consumed in excess. This carries some risk for their intended users (e.g. athletes), but a greater risk for children (who may be accidental consumers) due to their smaller body weight.

2.2 Regulatory gap – addition of caffeine to foods

FSANZ also found that additional measures are required to manage potential risks arising from caffeine being added to foods (other than FSSF as discussed above).

As noted above, some foods have express permissions to add caffeine (e.g. energy and cola drinks) and corresponding risk management measures.

A regulatory gap identified is that Code does not currently expressly prohibit or permit the addition of caffeine to food, except for specific prohibitions where caffeine is used as a food additive, or a processing aid, is a novel food or a nutritive substance. Submitters to P1054 and P1056 requested greater clarity in the Code on the addition of caffeine to foods that are not FCBs or cola drinks (see section 6 below).

Without clear regulation, if the addition of caffeine to food becomes more widespread, the risks of exceeding the recommended maximum limits of caffeine may increase. As noted by one submitter to the 1st CFS, the food industry globally is continually developing and innovating products to meet consumer expectations and desires and this may include caffeinated products (NZFGC 2023).

This has the greatest impact on sub-populations that are at higher risk, which includes infants, pre-schoolers, pregnant women and their unborn infants.

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[11] In this report, non-protein sports nutrition products include both foods regulated by the Code and other products not regulated by the Code

[12] Undertaken for the cost and benefit analysis for the 2nd CFS

2.3 Regulatory gap – provision of adequate information

An objective of the FSANZ Act is the provision of adequate information relating to food to enable consumers to make informed choices. As there is no permission for the addition of caffeine to FSSF, there are currently no requirements in the Code for information specifically about caffeine to be provided.

A scan of products available on the market indicates that almost all caffeinated FSSF do provide a degree of information about caffeine voluntarily. In addition, all FSSF are required to be labelled with a warning statement[13] but the existing warning statement is not specifically related to caffeine.

The lack of requirements relating to caffeine has resulted in information being provided inconsistently for FSSF. A review of the labels of a selection of caffeinated FSSF on the market found inconsistencies in:

- whether caffeine is listed within the nutrition information panel, or elsewhere on the label
- where caffeine is listed within the nutrition information panel, which can be exacerbated by caffeine being included within a list of numerous other nutrients
- the name used to describe caffeine (e.g. caffeine, anhydrous caffeine, caffeine anhydrous, caffeine monohydrate)
- the practice of listing caffeine as a subcomponent of another item, for example coffee bean extract.

Information being presented consistently is important to consumers. Research undertaken for P1028 (Infant formula) found that the majority of consumers who responded to a survey agreed that listing nutrients in the nutrition information panel in the same order across all products would make product comparison easier[14] and in a focus group study consumers preferred a nutrition information statement with a prescribed order to nutrition information statements (from products on the market) which did not have a standardised order (FSANZ 2022). This is consistent with earlier research on the nutrition information panel (FSANZ 1999), including a survey of consumers that found that consistency in nutrient order was important to 90% of consumers (TNS 2004).

Consistent names or terminology is also important for consumers. In the same research for P1028 the majority of consumers had the view that different terminology (e.g. different names for sugar) can make checking nutrients in foods difficult for consumers (FSANZ 2022). In an earlier study, a survey of consumers found that consistency in-specific wording on the nutrition information panel was important to 94% of consumers (TNS 2004).

Studies have also found that some consumers value standardised information as important for accountability and validating product marketing claims made by manufacturers (FSANZ 1999). For example, quantified caffeine content information can be used by a consumer to validate that a product marketed as pre-workout contains sufficient caffeine for that purpose.

The above factors may impact consumers' ability to find the information they need, as well as their understanding or trust of the information provided. The lack of labelling requirements for caffeine in FSSF therefore may make it difficult for consumers to make informed choices.

Consumer misunderstandings about caffeine content can also increase the risk of inadvertent excess caffeine consumption.

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[13] 'Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision'

[14] Agree 76% (Australia) and 77% (New Zealand), neither agree nor disagree 18% (Aus) and 17% (NZ), disagree 6% (Aus) and 6% (NZ)

A lack of consistency in how information is provided can also impact government enforcement agencies. Information provided on product labels is significantly easier (in terms of time and cost) for agencies to collect than other methods of information collection, such as analytical testing.

3 Why is government action needed?

Government action is needed to update the Code to address the problems identified above.

The Code has demonstrated capacity to successfully intervene to reduce the risks associated with caffeine.

An example of this is the regulation applying to energy drinks. As noted above, energy drinks are regulated by Standard 2.6.4, which specifies compositional limits for caffeine and also requires that information be provided to consumers to assist them to safely manage their caffeine intake. There is generally high compliance with labelling and compositional requirements of the Code.

Government action is needed to:

- **Adress risks to public health and safety**

Caffeine is a substance that has maximum safe daily intake levels. This means that caffeine is a hazard when consumed beyond safe levels. Also noted above, FSANZ has identified that more risk management is required to protect public health and safety against this potential hazard.

- **Improve quality of information provided**

The provision of information related to food is foundational to an open and transparent food market. It is a precondition for consumers to be able to make informed choices about the food they purchase and consume.

Using the Code as a mechanism to provide information related to caffeine in food provides industry with a standardised approach, resulting in consistency in information provided to consumers and how it is provided. As noted previously, consistency and standardisation are important for consumers, particularly for the nutrition information panel, where caffeine is most commonly declared (when permitted) under the status quo (and will be required to be declared under the proposal as described in the next section).

Voluntary industry standards for example are less likely to be effective at solving the problems identified above than changing the Code.

Effective voluntary industry standards generally requires that all members of an industry are members of an industry group, to enable joint rules to be set and enforced (Australian Government 2007).Quality and consistency of information provided is important in FSSF. FSANZ is not aware of an industry group that all or a majority of sports food manufacturers are a member of. The outcomes of the 1st and 2nd CFS support this, the industry groups that responded noted that they only represented a small proportion of the sports foods industry, or that only some of their membership manufactured FSSF (CMA 2025, NZFGC 2025).

Therefore, a change to the Code that would provide standards on the provision of information would likely be a more effective strategy.

3.1 Desired outcomes of the proposal

The desired outcomes of this proposal are based on the objectives of the FSANZ Act overall[15], modified for the unique nature of the proposal.

These desired outcomes are to:

- minimise the risk of overconsumption of caffeine (especially for vulnerable people)
- provide a means for FSSF to assist sports people in achieving specific performance goals
- provide adequate information to enable consumers to make an informed choice, and for governments to monitor the market and enforce the Code
- provide an effective regulatory framework within which the food industry can work efficiently.

Success at achieving these outcomes can be monitored in two ways:

- monitoring products on the market, and determining whether products on the market (particularly FSSF) meet these objectives
- monitoring health outcomes, to determine whether consumers are being protected from serious negative health consequences for caffeine.

Potential methods for evaluating the success of the proposal at achieving the objectives are discussed in more detail in section 8.

4 What options are to be considered?

FSANZ has considered a number of different approaches to address the identified problem.

These potential amendments and why they were not adopted as part of the proposal are summarised in the Appendix A.

The following analysis in section 5 identifies the costs and benefits to the community, government, and industry that may arise from these options.

At the 1st CFS, FSANZ considered three options, including the use of a standalone education campaign as an alternative to regulation during the standard development process (which was presented as 'Option 2'). However, this option was not supported by submitters and discarded.

At approval stage, FSANZ is considering two options:

- Maintaining status quo
- Regulatory option – a series of amendments to the Code.

4.1 Option 1 – Maintaining status quo

When considering any changes to regulation, FSANZ includes the status quo to compare other options against. If FSANZ's assessment leads to the decision to maintain the status quo, proposal P1056 would be abandoned.

Under this option, the current provisions for caffeine in the Code would remain unchanged. However, the food market would continue to evolve.

FSANZ has concluded that the status quo does not effectively manage the safety risks associated with caffeine. This has previously been discussed in section 2.

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[15] *See Section 3 of the FSANZ Act*

4.2 Option 2 - Proposed amendments

To address the problems identified, FSANZ has developed a package of amendments to the Code. The package of amendments is a blend of different risk management approaches that respond to the different nature of the products impacted and the associated risk.

The proposal will impact all foods that fall into one of the following categories:

- general foods with added caffeine – except where caffeine is added for a permitted purpose in the Code
- sports foods containing caffeine from any source

The proposed amendments are presented in some more detail in Table 4.1 below, and in full in the Approval Report.

At a high level, the proposed changes are:

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

The proposal will not impact foods such as coffee, teas and chocolate that naturally contain caffeine with the exception of coffee containing beverages that exceed the safe 200 mg limit per serve.

4.2.1 Summarised list of proposed amendments to the Code

The set of proposed amendments has been formulated based on a robust body of evidence and informed by three rounds of stakeholder consultation.

Each element of the proposed amendments to the Code is summarised in the following table.

For more detail on the proposal refer to the Approval Report which contains:

- a description of the changes in detail
- reasons behind each change in detail
- the proposed amendments to the Code text, and explanatory statement.

Table 4.1– High-level summary of proposed changes to the Code

Type of change	General foods		FSSF	
	Proposed changes to the Code	**Reason for the proposed change**	**Proposed change to the Code**	**Reason for the proposed change**
Clarifying whether caffeine can be added or sold as a food	Expressly prohibit selling pure caffeine or guarana extract (see below) as a food for retail sale or adding caffeine to foods (unless permitted elsewhere in the Code). Clarify, by way of an example, when caffeine can be present, as an ingredient or component in food by natural occurrence (for example cocoa). Caffeine can be added to foods where an explicit permission exists (for example energy drinks).	This prevents a trend towards more caffeine being added to the food supply without appropriate risk management, reducing the risk of excessive consumption especially by vulnerable populations. Applications can be made to amend the Code (under existing provisions) to allow caffeine to be added for specific purposes. As a result, each specific use of caffeine will be risk assessed if an application is made in the future.	Expressly permit adding caffeine to formulated supplementary sports foods (FSSF).	Creates an explicit permission which provides regulatory certainty for industry and government. Addition of caffeine to sports food at or below the maximum 200 mg one-day quantity (see below) is consistent with the FSANZ risk assessment and the purpose of FSSF (i.e. assist in achieving specific nutritional or performance goals).
Restrictions on the use of guarana extract	Expressly prohibit selling guarana extract (as defined by the Code) as a food or adding guarana extract to a food (unless that food is permitted to contain added caffeine)	Guarana extract can contain significantly higher concentrations of caffeine than other natural sources of caffeine (i.e. tea, coffee). This change effectively treats guarana as if it is added caffeine, for the same reasons identified above.	No restriction is proposed on adding guarana in any form as a source of caffeine to FSSF subject to the new compositional requirement.	
Limiting caffeine content, by amount	No change		Expressly permit up to 200 mg per one-day quantity. Directions on the label must not direct a person to consume more than 200 mg of caffeine per day from that sports food.	This intends to address the safety risks of excess caffeine consumption. Evidence shows it is safe to consume a single acute dose of 210 mg of caffeine, and 400 mg per day or under. These doses are not associated with significant adverse effects in the general adult population.

Type of change	General foods		FSSF	
	Proposed changes to the Code	Reason for the proposed change	Proposed change to the Code	Reason for the proposed change
				The 200 mg limit recognises that consumers are consuming other sources of caffeine (SD2 and SD3). Evidence also shows that 200 mg is effective to improve time trial performance in certain sports.
Limiting caffeine content, by proportion of product	Remove the existing concentration limits of 1% for liquids and 5% for solid and semi-solid foods (including powders).	Products that exceed this concentration level may be regulated by the TGA (2020b). A concentration limit across the Code is not needed due to the prohibition on the sale or addition of caffeine. Compositional limits exist where caffeine is specifically permitted.	Retain the concentration limits of 1% for FSSF in liquid form and 5% for FSSF in powder form.	This intends to address safety risks (identified in P1054) in FSSF where high amounts of caffeine can be present in small serving sizes, which are difficult to correctly measure. The limits effectively set a maximum caffeine concentration that accounts for the weight of the sports food, reducing the likelihood of inadvertent excessive caffeine consumption.
Packaging	No change		Individual portions of ready-to-consume caffeinated solid or semi-solid (not powdered) FSSF in a multi-serve pack must be individually packaged, if caffeine in the total pack exceeds 200 mg. Each individual package must not contain more than 200 mg caffeine. Individual portions must be labelled with the advisory statement (see below), unless the package has a surface area of less than 30 cm^2.	This intends to address safety risks. There is a risk of exceeding the safe caffeine intake by consuming multiple individual portions at one time, especially for smaller products with relatively high caffeine content.

Type of change	General foods		FSSF	
	Proposed changes to the Code	**Reason for the proposed change**	**Proposed change to the Code**	**Reason for the proposed change**
Labelling	New requirements for coffee containing beverages, that contain 200 mg or more of caffeine per serve (as consumed) and bear a NIP. Impacted products must be labelled with an advisory statement to the effect that the food is high in caffeine and not suitable for children under 15 years of age, or pregnant or breastfeeding women Caffeine content must be declared in nutrition information panel.	Intends to address safety risks by providing safety information and enables informed choice. The advisory statement addresses the higher risks present for people with lower bodyweights (children under 15) and pregnant and breastfeeding women.	FSSF containing caffeine must be labelled with an advisory statement to the effect of 'contains caffeine', and a prescribed warning statement. Caffeine containing individually packaged portions (that meet the criteria set above), must also have the advisory statement. Caffeine content must be declared in nutrition information panel. An exemption applies from the caffeine related labelling requirements where the caffeine source is from cocoa, chocolate, decaffeinated tea and/or decaffeinated coffee only.	Intends to address safety risks by providing safety information and enables informed choice. The warning statement addresses the higher risks present for people with lower bodyweights (children under 15) and pregnant and breastfeeding women. Requiring the advisory statement on individually packaged products is intended to reduce the risk of inadvertent consumption and assist caregivers with preventing inadvertent consumption for children (who are at higher risk). The exemption prevents the new requirements applying to products with negligible amounts of caffeine.

5 What is the likely net benefit of the options?

This section contains the consideration of the costs and benefits of the proposal.

In assessing this proposal, FSANZ is required by the FSANZ Act to have regard to whether the costs that would arise from the proposed measure outweigh its direct or indirect benefits.

Two options have been analysed in this section:

- Option 1 – status quo
- Option 2 – amend the Code

5.1 Impacts of Option 1 – status quo

There would be no change to the Code under Option 1as a result, the problems identified above will continue under the status quo.

Note that while the regulations would not change, the market for caffeinated products would continue to change. This means that the problems identified may increase or decrease in magnitude, while the regulations would remain unchanged.

5.2 Impacts of Option 2 – amend the Code

5.2.1 Introduction – scope of analysis

The analysis of the costs and benefits of this proposal is based on the best available evidence of the products on the current market. This means that for the purpose of this analysis, products have been assumed to be formulated in a way that is compliant with the Code.

This analysis therefore concludes that impacted products (in particular sports food products, which will be impacted to a greater extent) will incur costs to meet new requirements under Option 2.

FSANZ is, however, aware that a number of products on the market may not be considered compliant under the Code and as such, the costs to industry presented below may be overestimated.

Further, sports supplements that are classed as therapeutics and regulated by the TGA are not impacted.

See Appendix C of this report for further details on the analysis of the number of products in and out of scope.

FSANZ has only quantified where possible and/or directly considered the potential costs and benefits experienced by Australian and New Zealand businesses, consumers and governments. This is standard practice for government cost and benefit analyses (OIA 2023a, OMB 2023).

The analysis assumes that the proposed amendments to section 1.1.1—10 will apply to supplemented foods under the *New Zealand Supplemented Food Standard 2016*[16] and has included these products, where possible, in its analysis.

FSANZ's initial analysis indicates that approximately 60% of FSSF for sale in Australia and New Zealand are made in Australia or New Zealand.

[16] *See sections 1.4.5 and 2.5.1.3 in the 2nd CFS and 2.5.1 of the P1054 Amendment Report*

5.2.2 Summary of impacts for Option 2

The following table 5.1 summarises the potential impacts of Option 2, by stakeholder group.

The food industry includes manufacturers, importers, wholesalers and retailers of impacted foods. Governments include all levels of government, as all governments play a role in food safety.

Table 5.1 – Summary of impacts for Option 2, by stakeholder group and type of impact

Consumers	**Benefits**	Health benefits from reduced risk of caffeine overconsumption*
		Improved quality of information*
	Costs	Short term – potential higher cost of impacted foods* *(if passed on)*
		Potential reduction in choice of products* *(if withdrawn)*
Food industry		
FSSF	**Benefits**	Regulatory certainty on the ability to add caffeine safely*
	Costs	**Reformulation of products with more than a 200 mg one-day quantity – $A1.4m to $2.7m** *(may be passed on)*
		Relabelling to add required elements or update post reformulation – $A1.9m to $3.8m *(may be passed on)*
		Withdrawal of product varieties or lines* *(if reformulation or relabelling not viable)*
		Repackaging products that are caffeinated and ready-to-consume solid or semi-solid FSSF in a multi-serve pack, where entire packet contains more than 200 mg caffeine*
General foods	**Benefits**	Regulatory certainty on what caffeine can be added to*
	Costs	Reformulation (and consequential relabelling) of foods with added caffeine, guarana extract*
		Relabelling coffee drinks with more than 200 mg per serve of caffeine – $0.1m
		Potential withdrawal of product varieties or lines* *(if reformulation or relabelling not viable)*
		Withdrawal of guarana extract products (where sold as a food for retail sale)*
Governments	**Benefits**	Improved enforceability of food standards*
		Potential improvements in healthcare spending efficiency*
	Costs	*None identified*

* *Indicates impact not quantified*

5.2.3 Business impacts

This section discusses the impacts on businesses. In summary, the expected impacts for businesses are:

- quantifiable costs:
  - relabelling costs for FSSF that contain caffeine – A$1.9m to $3.8m one off cost[17]
  - relabelling costs for coffee containing beverages – A$0.1m one off cost
  - reformulation for FSSF to reduce caffeine below a 200 mg one-day quantity – $A1.4m to $2.7m one off cost[7]
1. unquantifiable costs:
   - repackaging (of individual caffeine-containing FSSF that are ready-to-consume solid or semi-solid in a multi-serve pack, where entire packet contains more than 200 mg caffeine)
   - product withdrawal (where adapting to the changes is uneconomical or not possible)
2. unquantifiable benefits
   - regulatory certainty

These impacts are explored in detail in the following sections.

This analysis considers the impacted food industry as a collective. Primary impacts will be experienced by manufacturers, with flow on impacts (or transfers) through the supply chain. In reading this impact analysis, care must be taken not to double count these transfers.

5.2.3.1 Transition period

The extent of the cost impact on industry is partially dependent on the amount of time provided for industry to become compliant with the amendments (CIE 2002).

Longer transition periods are more likely to reduce costs as they allow more businesses to use existing resources to modify their product range without needing additional resources as well as reduce the need to write-off of unused materials like packaging.

Longer transition periods also increase the likelihood that change can be aligned with business as usual reformulation and repackaging, as manufacturers develop new products to target trends in the market, reducing the marginal cost of the regulatory change.

There will be a two-year transition period for this proposal.

See section 7.3.3 for discussion on the rationale for the proposed transition period.

5.2.3.2 Costs for general foods – removing added caffeine

Caffeine will not be permitted to be added to foods for retail sale, except in circumstances where there is an existing permission.

This will not apply to caffeine that is present in a food ‘by natural occurrence’ but will apply to guarana extract.

Impacted products will need to be reformulated to remove added caffeine (including guarana extract) to continue to be sold.

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[7] *Costs experienced by manufacturers may be passed on to consumers. This is discussed at section 5.2.4.1*

Rather than be reformulated, some products could be:

- re-categorised as a sports food or energy drink[18], however these products would need to be relabelled
- withdrawn from the market.

The total cost impact of removing added caffeine from general foods for retail sale is expected to be small. Evidence suggests that few general food products contain added caffeine that would no longer be permitted. This finding is supported by stakeholders.

At the 1st CFS, stakeholders were asked if they agreed that few products on the market in Australia and New Zealand contained added caffeine. Of those that responded to this question, all either agreed or stated that they were unaware of any (AIS 2023, ALDI 2023, ATP 2023, NZFS 2023, SDA 2023).

In its response to the 1st CFS, New Zealand Food Safety stated that a search of the GS1 On Pack[19] database suggested there are relatively few general foods (other than energy drinks, cola-type drinks and FSSF) that contain added caffeine currently sold in New Zealand (NZFS 2023).

No additional information was received at the 2nd CFS, in response to FSANZ's conclusion that few general foods were impacted.

After the 2nd CFS, FSANZ amended the proposal to make it clear that caffeine from guarana extract is prohibited, unless caffeine is expressly permitted to be added to the food (e.g., FCBs and FSSF). FSANZ also introduced a new prohibition on the retail sale of guarana extract as a food.

FSANZ undertook a search of the Branded Food Database in October 2025. This search found less than 10 products that would potentially be impacted in Australia. The database is subject to limitations (see Appendix C for a description), however it does provide evidence that a small number of products on the market (in both Australia and New Zealand) contain guarana extract that might be impacted by the proposal[20].

A limitation of the Branded Food Database that it uses data from major supermarkets, which means that some products will not be captured. See Appendix C for more information about the Branded Food Database, and how it was used for this DRIS.

After the consultation paper, submitters generally supported the prohibition of the retail sale of caffeine and of guarana extract as foods for retail sale. Some submitters sought a definition of guarana extract. FSANZ has since amended the proposal to provide a definition for guarana extract to provide clarity on when guarana or guarana extract is captured by the prohibition.

FSANZ is aware of some imported products that will be impacted by the prohibition on adding guarana extract (unless permitted elsewhere in the Code). This includes guarana-flavoured soft drinks which are manufactured and exported globally from countries such as Brazil (Gootenberg 2023). Global products such as these are unlikely to be reformulated and instead will be withdrawn from sale in Australia and New Zealand, impacting domestic importers. Alternatively, such products can be reformulated as a cola beverage, using the existing permission in the Code for the addition of caffeine to cola beverages (which are 'soft drinks').

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[18] Subject to that product meeting the requirements of Standard 2.9.4 (FSSF) or Standard 2.6.4 (energy drinks)
[19] GS1 (NZ) On Pack is a service provided to New Zealand businesses that captures all label information on food products that have been opted-in by manufacturers.
[20] Guarana extract will still be still permitted as an ingredient in food, where caffeine is permitted to be added, for example the existing permission for FCBs and the proposed permission for FSSF

5.2.3.3 Costs for general foods – relabelling impacted coffee beverages

Some coffee containing beverages will have to be labelled with advisory statements and declare caffeine content in the nutrition information panel. This applies to beverages that:

- are packaged
- contain coffee
- contain 200 mg or more of caffeine per serving
- display a nutrition information panel
- is not an FCB or a FSSF.

Examples of products impacted by this requirement are flavoured (e.g. iced coffee) milk drinks and similar ready-to-drink coffee products, including canned coffee drinks.

FSANZ found a small number of products on the market that have the attributes above.

The specific requirements are to:

- provide an advisory statement to the effect that the food is high in caffeine and not suitable for children under 15 years of age, or pregnant or breastfeeding women.
- include the quantity of caffeine in the nutrition information panel.

For this group of products, generally caffeine is listed after calcium at the bottom of the nutrition information panel.

The estimated cost of relabelling products is expected to be less than $0.1m. This is a one-off cost and takes into account the proposed two-year transition period. This cost may be passed on to consumers in part or in full.

More information is provided on how this cost was calculated in Attachment B.

Submitters supported the approach proposed in the consultation paper. Some submitters suggested a warning statement should be required instead of an advisory statement, and that serving sizes should be standardised. FSANZ has maintained the approach taken in the consultation paper, ensuring the approach is commensurate to the risk posed by these products.

5.2.3.4 FSSF – about the industry

The exact size of the market for impacted FSSF is unknown.

However, data from Euromonitor (2024a, 2024b) shows that the entire category of non-protein sports food products (including products not impacted by this proposal)[21] sold, in 2024:

- A$313m in Australia, or 25% of the total sports food market
- NZ$7.7m in New Zealand, or 7% of the total sports food market.

Products found on the market are manufactured internationally as well as domestically.

There is no direct data on the size of the manufacturing industry for impacted products only. However, data from IBISWorld (2025) indicates that in Australia:

- there are approximately 85 businesses who manufacture vitamins, sports supplements and FSSF (noting that a number of these products are likely to be regulated as therapeutics)

[21] This category of products includes sport food products most likely contain caffeine, such as pre-workout powders. However other products within this category include recovery products like amino acid blends, and non-stimulant pre-workout products. Note that a small proportion of protein products also contain caffeine and will be impacted by the proposal.

- revenue for these manufacturers is A$2bn, of which A$508m (26%) is from sports and active nutrition products[22].

There is also limited evidence on the structure of the sports food industry. The top selling products by revenue (based on data from Euromonitor (2024a), Euromonitor (2024b)) originate from a small number of:

- large sized multinational manufacturers
- medium to large sized domestic manufacturers
- medium sized domestic importers and distributors.

However, these businesses represent only approximately one third of total sales by revenue. There are a significant number of small to medium business who manufacture or distribute the remaining products on the market. Based on the market scan, and with reference to the top selling products in the Euromonitor data, these businesses appear to sell a significant number of products with relatively small sales volumes. Evidence from the businesses' websites suggest that almost all of this cohort of small to medium businesses specialise in sports foods.

A significant proportion of products are exported, in part due to the reputation of the domestic industry as being 'clean' and safe (IBISWorld 2025). KPMG (2020) estimates that 14% of all sports foods produced in Australia are exported. Similar data was not available for New Zealand.

Products found on the market are sold through:

- domestic businesses, online or in-store
- international businesses online, direct to consumers or through retailers.

5.2.3.5 Number of impacted caffeinated sports foods

FSANZ's estimate is that there are approximately 350 impacted FSSF products that contain caffeine on the market. These products are sold as an estimated 1,800 stock keeping units (SKU), which are different pack sizes and flavours of the individual products.

The estimated number of impacted products and SKUs impacted is based on a desktop search of products on the market by FSANZ[23]. A number of assumptions have been made in collecting and analysing this data. Refer to Appendix C for more information. Appendix C contains:

- the search method for impacted products
- a summary of statistics on the products found
- the method used for calculating how many products are impacted.

At the 2nd CFS, FSANZ invited stakeholders to review the estimated number of products and the methodology used, and comment on whether the estimate is accurate or how it can be improved. No comments were received.

In the 1st CFS, FSANZ requested data from stakeholders on the number of SKUs impacted. A small number of companies provided a list of their SKUs. This was used to assist in validating the desktop search. No data was provided for the entire market.

[22] Note that this includes products out of scope for this proposal, including non-caffeinated products and therapeutic goods

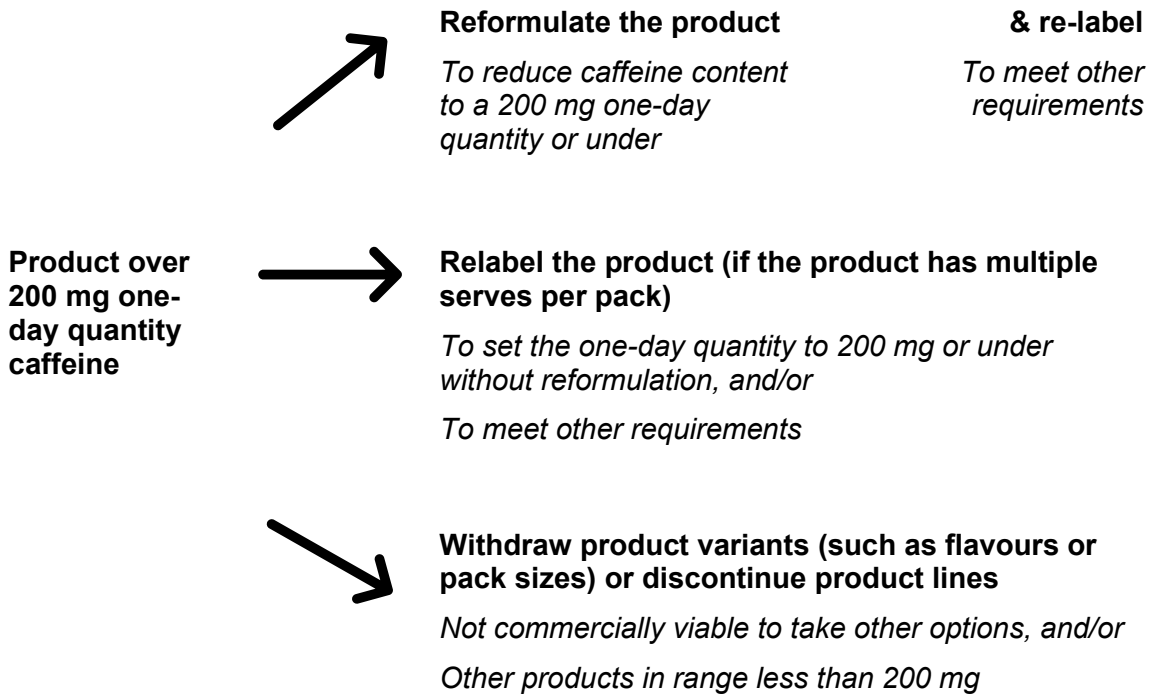
[23] Costings are based on what is currently marketed as a sports food regardless of its composition and purpose, it is not based on products that meet the current regulatory requirements as per Std 2.9.4.

5.2.3.6 Assumptions on business behaviour

The proposal will have financial costs to impacted businesses. Each business will decide on whether to adapt products, and how. Ultimately, this will depend on the strategic goals of the business and whether there is a return on investment in adapting the product.

For impacted FSSF containing over a 200 mg one-day quantity of caffeine, the options available are summarised below.

Figure 5.1– Likely business responses to 200 mg caffeine one-day quantity, for products over the limit



For the analysis of costs that follows, FSANZ has made a number of assumptions on what businesses will do in response to the proposal (discussed below).

Product lines may also be discontinued where reformulating a product line would result in that product replicating a product line the brand already has on the market. For example, a brand has multiple formulations of the same product type (for example pre-workout), and some products have more than a 200 mg caffeine one-day quantity, and some less than a 200 mg caffeine one-day quantity. It has been assumed in this circumstance all products over the 200 mg one-day quantity will be discontinued. Refer to Attachment B for more information.

To estimate the impacts, the total costs have been presented as a range to overcome the lack of data on industry behaviour.

5.2.3.7 Cost of relabelling impacted FSSF

FSSF containing caffeine will be required to:

- declare caffeine content (in milligrams) in the nutrition information panel, after sodium
- be labelled with an advisory statement to the effect of 'contains caffeine'
  - this statement must also be provided on the packaging of individual portions, in certain circumstances
- be labelled with a prescribed warning statement

- include directions for use that direct consumers to consume no more than 200 mg of caffeine per day from that sports food[24].

An exemption to these requirements applies where the source of caffeine is chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee only. For example – the exemption would apply to chocolate flavoured protein powders that contain no other sources of caffeine, other than chocolate or cocoa.

It is expected that all impacted FSSF containing caffeine currently on the market would require relabelling (to different extents) to continue to be sold. This is based on a review of products on the market with more information provided at Appendix C.

All products will be impacted because, in all products found:

- caffeine is not included in the nutrition information panel after sodium
- products do not have the warning statement required.

In these cases, minor label changes will be needed to adjust the nutrition information panel and amend warning statements already required to be provided.

For other products, changes will be more significant. For example, a number of products have directions on how to consume multiple servings at one time, which would result in a dose of more than 200 mg of caffeine. These directions are often present in the nutrition information panel, and product consumption directions. These are more significant label changes, which take more hours to complete. FSANZ estimates that between 480 and 970 products will require relabelling, this includes different flavours, different packet sizes and different packet formats[25] of the same product.

The estimated cost of relabelling FSSF is A$1.9 to A$3.8m. This is a one-off cost and takes into account the proposed two year transition period. This cost may be passed on to consumers in part or in full, see section 5.2.4.1 for further discussion.

The cost is presented as a range, as there is considerable uncertainty about how businesses will behave in response to the proposal.

More information is provided on how this cost was calculated in Appendix C.

Important caveats to this cost are:

- it only includes the costs for Australian and New Zealand businesses
- it assumes some SKU or product lines are withdrawn.

The total cost includes the cost of:

- administration (e.g. project management, contract management)
- label re-design
- market testing
- developing proofs, engraving plates and colour matching
- reviewing samples.

The cost per activity is broken down at Appendix C.

At the 2nd CFS, FSANZ invited stakeholders to review the estimated cost to relabel products and the methodology used, and comment on whether the estimate is accurate or how it can be improved. No comments were received.

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[24] For example, this prohibition would specifically prohibit the practice (seen in a scan of products on the market) of presenting a column in the nutrition information panel quantifying the amount of caffeine in two servings of a product

[25] For example, some products on the market are sold in both multiple serve tubs, and single serve sachets

FSANZ expects this cost will disproportionately impact small to medium businesses as a proportion of their revenue. Large multinational and domestic companies have diverse product ranges, and the cost is potentially proportionally smaller relative to their revenue from all products sold. However, small to medium businesses have less diverse product ranges and are more likely to have a large proportion of their product range impacted. In addition, the smaller the business, the less resources there are available to allocate to relabelling products.

5.2.3.1 Cost of reformulating impacted FSSF

FSSF will be permitted to contain up to a 200 mg one-day quantity of caffeine.

FSANZ estimates that 60% of caffeinated FSSF on the market are above the 200 mg one-day quantity threshold. FSANZ estimates that between 180 and 360 Australian and New Zealand products may to be reformulated, this includes different flavour variations of the same product.

The estimated cost of reformulating FSSF is A$1.4 to A$2.7m. This is a one-off cost and takes into account the proposed two year transition period. This cost may be passed on to consumers in part or in full, see section 5.2.4.1 for further discussion.

The cost is presented as a range, as there is considerable uncertainty about how businesses will behave in response to the proposal. More information is provided on how this cost was calculated in Appendix C.

Important caveats to this cost are:

- it only includes the costs for Australian and New Zealand businesses
- it assumes some SKU and product lines are withdrawn.

The total cost includes the cost of:

- research
- sample development and testing
- re-costing
- updates to sales and technical documentation.

This cost is based on analysis by Noetic for the TGA of the cost of reformulating sports foods that were expected to be captured by a change to therapeutic goods regulations (TGA 2020). This is the best available indication of the reformulation cost at the time of writing this analysis.

As noted above, it is possible that not all of these products will require reformulation. In some cases, for products sold in packages with multiple serves, the serving sizes or the recommended number of servings per day could be adjusted down while the underlying product remains the same. In this case, for multi-serve products the only cost would be to relabel the product which businesses will already incur to comply with other elements of the proposal. Therefore, this element of the proposal will not result in any additional costs for this cohort of products.

However, due to lack of evidence on how businesses will respond to the change, FSANZ has taken a conservative approach and assumed that no products providing over a 200 mg one-day quantity of caffeine will relabel instead of reformulate, which provides an upper bound estimate of likely costs.

At the 2nd CFS, FSANZ invited stakeholders to review the estimated cost to reformulate products and the methodology used, and comment on whether the estimate is accurate or how it can be improved. No comments were received.

FSANZ expects this cost will disproportionately impact small to medium businesses, for the reasons described above.

5.2.3.2 Cost of repackaging some FSSF

Individual portions of caffeinated FSSF, sold together in a package of multiple portions, will be required to be individually packaged where the multi-pack contains:

- multiple individual portions
- more than 200 mg of caffeine (adding all portions in the package)
- a product that is:
  - solid or semi-solid (excluding powders)
  - not designed for individual sale
  - ready to consume.

An example of an impacted product is a packet of multiple caffeinated pre-workout gummies. Under the proposal, each serving of gummies would be required to be separately packaged into portions containing no more than 200 mg of caffeine, within the multi-pack if the above conditions applied.

The total cost of this element of the proposal is unknown, due to lack of data on the cost of repackaging products.

Based on the market scan, there is expected to be few products impacted by this change, and therefore the total cost is small.

At the 2nd CFS, FSANZ encouraged stakeholders to provide data which would enable the total cost to be estimated, and comment on whether the conclusion that the impacts are likely to be minor was correct. No comments were received.

5.2.3.3 Costs of impacted products being withdrawn

In some cases, the cost of adapting to the regulation may not be a worthwhile investment. This may mean some flavours or packet sizes are not updated, to minimise costs. Some product lines may be withdrawn or discontinued.

This impact represents an opportunity cost for the industry, of profit that will not be realised because of the proposal. The net impact for industry will depend on what businesses decide to invest in instead, and the relative profit margin of that investment compared to the discontinued product.

Imported products are more likely to be withdrawn. This is because it is less likely that international manufactures will achieve a return on investment for adapting products to a relatively small market like Australia and New Zealand (TGA 2020).

Due to a lack of data, the cost of products being withdrawn has not been quantified.

5.2.3.4 Benefit of regulatory certainty for industry

Updating the Code may provide businesses:

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

In consultation, some industry stakeholders stated that currently there are different interpretations of how the Code regulates caffeine, and greater certainty and clarity would be beneficial (AFGC 2023, NZFGC 2025) and supports innovation (ABC 2023, Frucor Suntory 2023).

Less clarity in how the Code should be interpreted increases the risk that enforcement agencies view products as non-compliant (where businesses have a different view), therefore increasing the risk of enforcement action and potentially interrupting or delaying the supply of their product (FSANZ 2015). This can result in expenses related to product recalls (including the cost of having to dispose of recalled products), potential court costs and damage to a business' reputation.

Therefore, regulatory certainty is likely to lower regulatory risk and may reduce costs and increase investment. The magnitude of this benefit will be greater for FSSF, as it will clarify what is permitted, creating more potential for greater investment in this category.

For FSSF, businesses will benefit from certainty on:

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

For general foods, businesses will benefit from certainty on:

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

Domestically produced supplements and sports foods have a reputation as being 'clean' and 'safe' in international markets, which enables domestic manufacturers to capture more of the export product market (IBISWorld 2025). It is expected that this proposal will further improve this reputation, by further improving the safety of these products.

Clear and evidence-based regulation may also improve consumer confidence within the domestic market increasing sales.

5.2.4 Consumer impacts

In summary, the impacts on consumers are:

- Costs
    - Potential short-term increases in the cost of impacted products (transfer of costs by business to consumers)
- Benefits
    - Potential health benefits from reduced risk of over consumption of caffeine
    - Greater availability of information

These impacts are explored in detail in the following sections.

5.2.4.1 Costs for consumers

In the short-term, some businesses may pass on some (or all) of the increased costs of meeting the new standards (as discussed in section 5.2.3) to consumers through higher prices of impacted products.

If passed on, the majority of costs would be experienced by consumers of FSSF products. Consumers of impacted general foods (some coffee containing beverages and food with added guarana extract) may also experience higher costs but to a much lesser extent.

The extent that businesses will pass on costs to consumers depends upon a number of factors (CIE 2008). The most significant factor is the price responsiveness of customers (also known as demand elasticity). The more price-responsive customers are the less likely full cost pass through will occur. That is to say, if businesses raise prices too high, consumers will purchase other goods instead.

FSANZ does not have data or a model to estimate the price responsiveness of impacted products.

However, the extent of costs being passed on is higher on products that:

- are a premium product
- have fewer substitutes that are readily accessible.

Caffeinated FSSF are more likely than not to have these attributes. Caffeinated FSSF are sold at a higher price point than other equivalent sources of caffeine such as instant coffee, and there are few substitutes to pre-workout powders (the most common caffeinated product) that have the same level of convenience, caffeine content, and other product features (like additional substances).

Therefore, it is more likely that a significant proportion of the costs will be passed on for impacted FSSF.

As noted in section 5.2.3.3, some products may be withdrawn. Where this occurs, consumers will experience a reduction in product choice.

Over the longer-term prices of FSSF may decrease. This is because the proposal (as noted in section 5.2.3.4) increases regulatory certainty and therefore incentivises investment. Increased investment can lead to increased firm entry and therefore price competition (CMA (UK) 2023).

5.2.4.2 Health benefits ordinary adults

This section describes the health benefits for ordinary adults, who have average levels of caffeine consumption and no special caffeine related risks such as caffeine sensitivity or pregnancy (discussed in section 0). The benefits for high caffeine users are discussed in the following section.

As discussed in section 1.82, caffeine consumption can have a negative impact on a person's health and wellbeing, if it is consumed at a level beyond what they can tolerate or what is safe.

This proposal would lower the amount of caffeine in the food supply and may also prevent a trend towards greater caffeination.

This reduction may result in a small reduction in daily caffeine consumption at an individual level, which may be enough for some consumers to experience minor improvements in health, as outlined in the table below.

Table 5.2 – Potential benefits from small reductions in daily caffeine consumption (adults)

Benefit for the individual	Benefit for society
Benefit of improved quality of life, from: • improved sleep • reduced blood pressure • reduced anxiety	Increase in aggregate wellbeing

The social science literature review (SD 3) found evidence of common perceived side effects of caffeine consumption, including heart palpitations, tremors, migraines, diarrhoea, dehydration, insomnia, irritability and headaches.

Data provided to FSANZ by the National Poisons Centre (NZ) shows that common symptoms after suspected excess caffeine consumption include abdominal pain, vomiting, jitteriness, shaking, racing heart, sore chest, and difficulty sleeping.

The estimated usual mean daily intake of caffeine in adults is summarised below, based on data from the dietary exposure assessment.

Table 5.3 – Estimated usual mean, median and 95th percentile dietary caffeine intakes, by gender and country

		Mean (mg)	Median (mg)	95th percentile
Female	**Australia**	162	134	393
	New Zealand	124	118	282
Male	**Australia**	172	143	420
	New Zealand	142	134	323

Note: adults defined as 20 years and above for Australia, and 15 years and above for New Zealand.

The safety assessment for caffeine identified that poor health outcomes, such as poor sleep and anxiety can occur from doses of 100 mg or more.

It is unclear how many ordinary adults would experience a health benefit as a result of the proposal. However, evidence from the dietary exposure assessment (SD 2) and the social science literature review (SD 3) show that almost all adults (87 to 99%) consume some caffeine.

Therefore, there is the potential for the proposal to achieve the outcomes listed in Table 5. for a large proportion of the population, given the average consumption level is above the level where effects have been reported to occur.

A reduction in caffeination of the food supply may be more effective for some consumers at reducing caffeine intake (and improving health outcomes in the manner suggested in Table 5.) than providing more information on product packaging.

As noted in the social science literature review (SD 3), there was a lack of evidence on consumer awareness of the daily maximum limits of caffeine and whether consumers are aware of the caffeine content associated with foods that naturally contain caffeine such as tea and coffee.

However, there is evidence that consumers may not always be aware that caffeine has been added to beverages.

In addition, the assessment found that most consumers from the broader population reported perceived negative side effects from consuming caffeinated food and beverage products. However, this did not always cause consumers to reduce their caffeine intake.

5.2.4.3 Health benefits for higher caffeine consumers

The proposal may have more significant health benefits (due to a greater reduction in risk) for the cohort of consumers who currently consume higher caffeine dose FSSFs and/or consume higher amounts of caffeine over the day relative to ordinary adults (as described in the previous section).

However, as these doses are more extreme, the frequency of these benefits being achieved is likely to be rare.

These benefits may come from FSSF specific elements of the proposal, as well as the potential reduction in caffeination of the overall food supply. FSSF elements of the proposal that may lead to this benefit include:

- the 200 mg composition limit
- improved consistency of labelling, leading to improved consumer understanding of caffeine intake
- suggestions or directions on how to consume more than 200 mg per day removed from product labels.

The safety assessment (SD1, section 2.4) found that acute doses 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 has been reported at a dose of 3000 mg, however it is more commonly associated with doses of around 5000 to 10,000 mg of caffeine.

The following table summarises potential the potential health benefits of the proposal for higher caffeine users.

Table 5.4 – Potential benefits for high caffeine users (adults)

	Benefit for the individual	Benefit for society
Health benefit	• reduced risk of cardiac arrest • reduced risk of seizure • reduced risk of death • improved treatment in emergency care (due to improvements in product information)	• increase in aggregate health and wellbeing
Financial benefit	• reduced health expenses • reduction in lost income and lost leisure time	• reduction in health care costs • reduction in absences from work, lost productivity

It is unclear how many people are at risk of serious harm from caffeine and would therefore benefit from a reduction in risk.

Evidence from the dietary exposure assessment suggests that up to 6% of adults exceed the recommended levels. The social science literature review (SD 3) found studies that showed 14% and 17% of the broader population may be regularly exceeding the recommended daily limit of 400 mg per day.

It is not known what proportion of this cohort are at risk of serious harm from caffeine consumption. However, there is some evidence of serious health outcomes arising from caffeine, which may be less likely to occur as a result of the proposal.

NSW Poisons Information Centre (NSWPIC 2023) provided an example of one case in response to the 1st CFS:

A 17 year old male who had been using a pre-workout and decided to use "a bit extra" one day, resulting in vomiting, a heart rate of >140BPM requiring management in hospital.

5.2.4.4 Health benefits for pregnant women

Pregnant women may experience additional benefits from the proposal.

Pregnant women are also more likely to benefit from preventing a potential trend toward caffeination of the food supply, which is likely to increase the risk of inadvertent consumption of caffeine. Data demonstrates that most pregnant women do consume an amount of caffeine (SD2, section 3.1) (SD3, research question 2), and therefore increased caffeination of other foods may increase the risk of overconsumption.

The safety assessment concluded that available evidence on the effects of caffeine generally supports the recommendation that pregnant women should limit their caffeine intake to less than 200 mg caffeine per day. This is half the 400 mg daily recommended dose for adults generally (SD1, section 2.6).

Pregnant women experience the same effects of caffeine as the general adult population.

However, the safety assessment also found evidence of potential adverse effects on the fetus of high caffeine consumption during pregnancy including:

- miscarriage
- stillbirth
- fetal growth restriction.

It is unclear how many pregnant women are at risk of serious harm from caffeine. However, evidence from the social science literature review (SD 3) found that the majority of pregnant women studied either decreased or stopped caffeine consumption across all sources during pregnancy (between 64.9% – 77%).

Pregnant women are not likely to experience significant benefits from the application of the proposal to FSSF. This is because FSSF currently provide a warning to pregnant women stating: *Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision*.

5.2.4.5 Health benefits for children

Children experience the same effects of caffeine as the general adult population. However, for children the recommended safe dose of caffeine declines with body weight, therefore the smaller or younger the child the smaller the dose required for serious health impacts to occur.

It is likely that most benefits for children will be due to a reduction in inadvertent consumption. The dietary exposure assessment found (based on diet survey data) that no or few Australian children had a caffeine intake that exceeded the recommended maximum levels. The social science literature review (SD 3) also found that all but one study that examined caffeine intake in children reported levels of caffeine intake that are within, and often well under, the daily recommended limit for children in Australia. No data or studies were available for New Zealand.

However, there is evidence to suggest that children are at risk of accidental exposure.

Data from the New Zealand Poisons Centre[26] shows that, between 2017 and 2021, 45 calls for suspected caffeine exposure (of a total of 86 where age was recorded) where on behalf of someone aged 12 or younger. In Australia, data on age are incomplete in the records obtained by FSANZ from poisons centres, however the data obtained shows that pre-schoolers are frequent subjects of calls concerning caffeine exposure.

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[26] *See the safety assessment, section 2.4.1*

The safety assessment (SD 1) also found evidence of accidental exposure to caffeine for children in NSW (AUS), and the USA.

5.2.4.6 Benefits – improved information and informed choice

Consumers of FSSF, as well as impacted coffee drinks, are expected to benefit from improved information provision.

As noted in section 2.3, while information about caffeine content is generally provided voluntarily on impacted products, it is provided inconsistently.

The following table catalogues differences in how caffeine information is provided to consumers on caffeinated FSSF. The information in the table is based on a desktop review of products currently on the market.

Table 5.5 – Current labelling practices for caffeinated FSSF, and proposed labelling requirements

Labelling element	Examples of how products on the market provide caffeine related information	Proposed requirements
Names used for caffeine in the NIP	• Caffeine • Caffeine anhydrous • Anhydrous caffeine • Caffeine monohydrate • Di Caffeine Malate • Proprietary name for caffeine provided • Naturally occurring caffeine Ingredient name used (e.g. “green coffee bean extract, providing caffeine of x mg”)	• “Caffeine” line in the NIP
Location of caffeine quantity	• In the NIP, anywhere from after sodium to the bottom of the NIP • On the back of the product, not in the NIP • On the front of the product • In the ingredients list • Within a brand specific grouping of nutrients (e.g. focus blend) • Not provided	• Must be included in the NIP, after sodium
Presentation of caffeine quantity	• Total caffeine provided • Caffeine content divided across different sources of caffeine, no total provided • Milligrams of ingredient provided, of which x% is caffeine • Caffeine provided as a subcategory of an ingredient in the NIP	• NIP must include total caffeine from any source

As noted in section 2.3, consistent presentation and terminology is important to consumers making informed choices.

It is expected that removing the inconsistencies identified in the table above will help consumers make informed choices.

The social science literature review (SD 3) sought evidence on whether consumers feel they have sufficient information to enable them to make an informed choice regarding their caffeine intake. Limited evidence was found on this question, none of the identified studies looked at issues related to the inconsistency of information presented on FSSF.

Inconsistencies in how information presented is also a safety issue. As noted in the safety assessment, a lack of clearly understood labelling on FSSF creates a risk of caffeine overdose.

Many consumers are also likely to value the information required on label (see section 2.2.6 of the 2nd CFS) given its potential to support the safe and appropriate use of foods containing caffeine.

5.2.4.7 Caffeinated FSSF and performance benefits

The proposed 200 mg one day quantity is not expected to negatively impact consumers who consume caffeinated FSSF for the performance effects of caffeine.

FSSF are a special category of foods in the Code, defined in the Code as '*a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals*.'

In setting the 200 mg one day quantity, FSANZ considered the evidence on the ergogenic benefit of caffeine (SD 4) 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.

5.2.5 Governments' impacts

The proposed changes will benefit governments in Australia and New Zealand. The expected benefits are:

- improved clarity and enforceability of the standards
- increased healthcare spending efficiency.

These benefits are further outline below.

No additional costs to governments have been identified.

5.2.5.1 Improved enforceability

The Code is enforced by various food safety bodies, including:

- state, territory and New Zealand food safety regulators
- national border inspection agencies

Government stakeholders claim that currently there is 'ambiguity' and 'uncertainty' on how the Code regulates caffeine, and that greater clarity is required for the Code to achieve its intent.

A lack of clarity in how the Code should be interpreted can create challenges for food enforcement agencies in determining compliance of food products with the Code and in taking action against food products that are considered by the agency to be non-compliant.

For example, a food enforcement agency may advise the food manufacturer or supplier that they view a product as non-compliant and recommend the company cease supply. However, if the food company disagrees with the food enforcement agency's view, the matter may need to be decided in court, which can be costly and time consuming. The risk of court proceedings being decided in favour of the food company, due to the lack of clarity in the Code, may be too high for the food enforcement agency to be willing to pursue court action.

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

5.2.5.2 Improved health care spending efficiency

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

This saving may result in less health care expenditure or alternatively may result in governments being able to divert funding savings from this proposal to other health care priorities.

For the reasons identified in section 5.2.4, this benefit has not been quantified.

5.2.6 Assessment of proposal against international standards

This section assesses the proposal against international standards, as well as at the individual country level. Divergence between the Code and international standards can create barriers to trade.

In summary, there are no international standards applying to caffeine.

At the national or jurisdictional level, there are some differences between what is proposed for Australia and New Zealand and other domestic standards. The most significant difference is the compositional limit on sports food, which is expected to impact a significant number of imported caffeinated sports foods currently on the market particularly from the USA.

5.2.6.1 Codex standards

International food standards are developed by the Codex Alimentarius Commission (Codex). Codex develops international food standards, guidelines and codes of practice for an international food code that contributes to the safety, quality and fairness of food trade.

Codex standards are recognised by the World Trade Organization (WTO). As a WTO members, Australia and New Zealand are obliged, where possible, to harmonise their domestic regulations with Codex standards (including the Code).

The FSANZ Act provides (Section 13(d)) that one of FSANZ's functions is to promote consistency between standards in Australia and New Zealand with those used internationally, based on the best available scientific evidence.

Therefore, FSANZ takes Codex standards into account when developing and revising domestic food standards.

However, there are no relevant Codex food standards relating to the addition of caffeine to food.

5.2.6.2 National or jurisdictional level standards

In the absence of a Codex international standard, international food regulators have implemented different approaches to regulating caffeine.

At a national/jurisdictional level, there are no consistent standards for caffeine. At the 1st CFS (Attachment 2), FSANZ summarised some of the known regulations that apply to caffeine in other countries.

In many jurisdictions products (including sports foods) can be sold with caffeine per serve of more than 200 mg, including the United States. Up to 40% of caffeinated sports foods sold in Australia or New Zealand (by number of products) are manufactured in the United States[27]. Approximately 70% of this group of products have caffeine per serve greater than 200 mg[28].

Therefore, the 200 mg one-day quantity will prevent a significant number of sports foods manufactured internationally being sold in Australia or New Zealand.

This may impact on competition within the domestic market. However, impacts are expected to be limited, as products within the 200 mg one-day quantity can still be sold.

For general foods, there is minimal impact. Few impacted products sold in Australia or New Zealand contain added caffeine or guarana extract, which means that there will be limited impact on imported products.

The labelling aspect of the proposal does not add any additional barriers to entry in the domestic market, as product labelling requirements under the Code are unique to Australia and New Zealand under the status quo.

The proposal does not place any restrictions on domestic firms that would prevent products being sold internationally.

Manufacturers of supplement products have a strong reputation in terms of safety (IBISWorld 2025). The proposal may increase consumer confidence in international markets by further improving this reputation, which could improve the competitiveness of domestically produced products within international markets.

5.3 Conclusion of net benefit analysis

FSANZ's view is that Option 2 has a net benefit, the costs that would arise from the proposal do not outweigh the benefits. For this reason, it is the recommended option.

This conclusion is explained in more detail below.

5.3.1 Option 1 – status quo

By definition, the status quo will have no impacts.

This option is not recommended over option 2 which is expected to have a net benefit, as outlined in the section below.

5.3.2 Option 2 – package of amendments

FSANZ's view is that Option 2 has a net benefit, the costs that would arise from the proposal do not outweigh the benefits. The costs and benefits of the proposal are summarised in the table below. The table below presents impacts on a society wide perspective, therefore quantified costs may be experienced by industry or passed on partially or fully to consumers.

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[27] *Based on an analysis of FSANZ's market scan data*
[28] *Based on an analysis of FSANZ's market scan data*

Table 5.6 – Summary of costs and benefits for Option 2, by quantified or unquantified

Costs	**Quantified**	Reformulating FSSF with more than 200 mg per serve – A$1.4m to A$2.7m
		Relabelling FSSF to add required elements or update post reformulation – A$1.9m to A$3.8m
		Relabelling coffee drinks with more than 200 mg per serve of caffeine – A$0.1m
		Total quantified costs – A$3.4m to A$6.6m
	Unquantified	Withdrawal of product varieties or lines
		Repackaging impacted FSSF
Benefits	**Unquantified**	Health benefits from reduced risk of caffeine overconsumption
		Potential improvements in healthcare spending efficiency
		Improved quality of information for consumers
		Improved enforceability and regulatory certainty

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

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

A break-even analysis is a method of demonstrating the likelihood of a proposal achieving a net benefit when only a selection of costs and benefits are capable of being quantified (OMB 2023).

The break-even analysis apportions the quantified costs of the proposal over a 10-year period[29] (taking into account the time value of money) and then divides it by the number of sports food consumers over that period. In the break-even analysis, a consumer has been defined someone who consumes a caffeinated FSSF daily (based on data from the 2024 FSANZ Consumer Insights Tracker (FSANZ 2025)).[30]

While the cost of relabelling high caffeine coffee containing drinks relates to non-FSSF products, this consumer cohort was chosen to model the break-even benefits because consumers are most likely to benefit due to the higher concentration of caffeine in FSSF.

A break-even analysis was calculated for the 2nd CFS. This break-even analysis was updated for the additional consultation paper, to include the cost of relabelling impacted coffee drinks. It was updated again for this DRIS to incorporate CIT 2024 data (FSANZ 2025) which included new data for the proportion of daily users of products likely to contain caffeine.

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[29] Impact analysis guidance states that regulation impact statements should assume that regulations have a 10-year life, therefore the upfront cost of regulation should be apportioned over ten years

[30] A growth rate was not applied to the proportion of consumers consuming caffeinated sports foods, due to difficulties in reliably forecasting this over ten years, which means that the break-even amount may be lower than estimated

The break-even analysis shows that consumers, government and/or industry will need to receive benefit at the amount of $0.26 to $0.52 per year per daily user[1] of caffeinated FSSF (5.3% of adult population in Aus and NZ) for the benefits of the proposal to exceed the quantified costs.

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

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

As noted in section 5.2.2, caffeine can have minor impacts on people's wellbeing from doses of 100 mg or above including:

- sleep disturbance

  The total cost of inadequate sleep in Australia was estimated to be $66.3 billion in 2016-17, comprising $26.2 billion in financial costs and $40.1 billion in the loss of wellbeing. This equates to approximately $8,968 per person affected (39.8% of Australian adults) in both financial and wellbeing costs (SleepFit / Deloitte Access Economics Deloitte Access Economics 2017).

- higher blood pressure

  The prevalence of high blood pressure in Australia is significant, with 34% of adults estimated to have hypertension (ABS 2022). The estimated annual cost of treating hypertension in Australia in 2021–22 was $1.2 billion (Atkins et al. 2024).

- anxiety.

  Across their lifetime, 26.3% Australians and 24.9% of New Zealanders will have an anxiety disorder (RANZCP 2016). Anxiety disorders contributed 3.9% of the total disease burden in Australia (AIHW 2024).

The proposal could reduce the amount of caffeine consumed by users of FSSF through changes in product composition or improved information provided to consumers. This could then lead to a reduction in the severity or frequency of negative impacts linked to sleep disturbance, high blood pressure and/or anxiety.

6 Who was consulted, how was feedback incorporated?

Consultation is a key part of FSANZ's standards development process and is underpinned by a statutory consultation process. FSANZ consults with stakeholders to ensure we understand their business, and to seek information and advice to inform the proposal assessment and standard development

FSANZ also consults with members of the World Trade Organization, with the objective of promoting harmony with international standards to the greatest extent possible.

6.1 Who and how we consulted

Two CFS reports were released, one in December 2022 and the other in March 2025.

Following consideration of the 2nd CFS, FSANZ revised elements of its proposed approach. FSANZ sought submissions on the revised elements, releasing a consultation paper in October 2025.

All submissions (except confidential submissions) are released on the FSANZ website.[31]

6.2 First call for submissions

The 1st CFS consultation was held from 19 December 2023 to 13 February 2023.

The 1st call for submission included (as is standard practice) FSANZ's summary of the scientific evidence (SDs 1 to 4), a proposed risk management approach, but no draft amendments to the Code.

FSANZ received 22 submissions to the 1st CFS, these included:

- three from individual business
- six from industry peak bodies
- eleven from government agencies
- two from health-related peak bodies.

Most submitters to the 1st CFS supported regulation rather than a non-regulatory approach, to address the serious health consequences of inadvertent or excessive caffeine intake, to increase regulatory clarity and to protect vulnerable sub-populations.

Submitters generally supported the proposed express permission for FSSF to contain caffeine to a maximum of 200 mg per one-day quantity, and the proposed express prohibition on the addition of caffeine for all foods for retail sale unless expressly permitted.

Some submitters supported the removal of the P1054 variation while others stated the restrictions should remain in the Code so that products with a high concentration of caffeine could not be a food for retail sale.

Submitters supported the proposed approach to require an advisory statement of 'contains caffeine' on the label of all FSSF containing caffeine and there was no opposition from submitters to declaring the amount of caffeine and one-day quantity in FSSF. Some submitters recommended additional statements for FSSF.

Some submitters expressed concerns that a risk would remain for small volume FSSF that contain caffeine in the absence of concentration limits.

6.3 Second call for submissions

The 2nd CFS was held from 4 March 2025 to 15 April 2025.

The 2nd CFS contained (as is standard practice) FSANZ's summary of the evidence (with minor updates), updated risk management approach, and draft amendments to the Code.

FSANZ received 23 submissions to the 2nd CFS:

- nine from industry
- nine from government agencies
- two from academic institutes
- two from health-related peak bodies
- one from an individual submitter.

There remained general support for the 200 mg one-day quantity of caffeine in FSSF, while others opposed.

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[31] *https://www.foodstandards.gov.au/food-standards-code/proposals/p1056*

Submitter views continued to be mixed regarding removing P1054 prohibitions.

Submitters continued to support the proposed prohibition of caffeine from food for sale, or as a component of a food for sale, however, others thought there remained lack of clarity.

Submitters largely supported the proposed amendment to the mandatory warning statement for FSSF containing caffeine to include breastfeeding women.

Submitters similarly supported the proposed amendment that when a FSSF contains caffeine an advisory statement indicating that the food contains caffeine must be provided, and that a FSSF containing caffeine to have a mandatory declaration of caffeine in the NIP.

Submitters particularly raised concerns regarding:

- the prohibition of caffeine as a food and as an ingredient, naturally occurring caffeine and high caffeine coffee beverages
  - concerns regarding concentrated plant extracts high in caffeine and sold as food.
  - clarity around whether all sources of caffeine will be prohibited as an ingredient or compound (unless where expressly permitted).
  - unmanaged risks surrounding packaged beverages containing coffee with a caffeine content of greater than 200 mg per serve.
- labelling of FSSF:
  - regulatory burden of additional labelling of FSSF containing caffeine at any level.
  - whether individual portion packs of caffeine-containing FSSF would require labelling regarding caffeine.
  -

After consideration of stakeholder submissions to the 2nd CFS, FSANZ decided to propose changes to the proposed draft variations to the Code. The proposed changes were significant enough to warrant an additional round of public consultation with stakeholders.

Appendix 2 summarises the amendments made to the draft variation to the Code that was presented to stakeholders at the 2nd CFS.

Minor clarifications were also made, based on stakeholder feedback, which changed the way that amendments to the Code were expressed, but not the intention

6.4 Additional consultation paper

The additional consultation paper was released for public consultation on 31 October 2025 and closed for comments on 12 December 2025.

The Consultation Paper sought views on revisions to the draft variation relating to the retail sale of guarana extract and guarana extract as an ingredient, naturally occurring caffeine, high caffeine coffee beverages and labelling for certain caffeine-containing FSSF.

FSANZ received 25 submissions to the additional consultation paper.

- 14 from industry
- 5 from government agencies
- 1 from academic institutes
- 1 from health-related peak bodies
- 2 from individual submitters.
- 2 confidential submissions

Table 6.1 below summarises key stakeholder issues raised at the additional consultation that led to modifications to the proposal.

Minor clarifications were also made, based on stakeholder feedback, which changed the way that amendments to the Code were expressed, but not the intention.

Table 6.2 – Key stakeholder issues raised at the additional consultation that led to modifications to the proposal

Key issue	How feedback has been incorporated
Responses to the proposed prohibition on guarana extract as a food for retail sale and ingredient in food for retail sale was mixed. • Some submitters supported the prohibition in principle however sought clarification on the definition of guarana extract • Some submitters sought clarification on the use of guarana/guarana extract as an ingredient or flavouring rather than a source of caffeine to prevent unnecessary restriction on innovation and cost to industry disproportionate to the risk • Some submitters opposed the prohibition on guarana extract outright citing over prescriptiveness and inhibition of innovation, whereas some submitters supported the prohibition. • Some submitters sought an extension to the transition period to allow additional time for reformulation and relabelling	In response to these concerns, FSANZ amended the draft variation to set compositional parameters for the caffeine content of guarana extract. This definition would apply to guarana extract as a food for retail sale, and the use of guarana extract as an ingredient in food. The values align with the P1054 variation. There is therefore no impact on the retail sale of guarana extract at the concentration limits established, as the products are already prohibited under the P1054 variation. FSANZ has made a number of minor drafting amendments in response to stakeholder feedback to clarify the intent of the proposed changes and to demonstrate that the regulatory burden is significantly lower than some submitters anticipated.
Some submitters sought clarity in the drafting on other caffeine containing plant extracts, naturally occurring caffeine and stronger regulation on novel caffeine sources.	FSANZ's overall intent on caffeine by natural occurrence remains the same however small changes have been made to provide further clarity regarding guarana extracts and other plant extracts.

Key issue	How feedback has been incorporated
There was general support for the proposed labelling requirements for high caffeine coffee beverages and the proposed exemption from the labelling requirements when caffeine is present from certain ingredients in FSSF. There was general support for the proposed labelling requirement for certain FSSF in a multipack. • Some submitters proposed the advisory statement should apply to all FSSF in a multi pack regardless of size and some sought clarification that both the warning statement and advisory statement are required on the outer pack.	In the Consultation Paper, FSANZ proposed an exemption from certain caffeine-related labelling requirements for FSSF containing caffeine if the caffeine is present only from chocolate, cocoa, decaffeinated tea and/or coffee (including instant versions of these). Following release of the Consultation Paper, FSANZ has decided to also apply this exemption to the individual packaging requirement. FSANZ considers the regulatory impact of individual packaging on certain FSSF is not justified when caffeine is present only because of its natural occurrence in certain ingredients that have minimal amounts of caffeine (cocoa, chocolate, and decaffeinated tea or coffee). This approach is therefore more risk proportionate than that proposed in the 2nd CFS and reduces the regulatory burden of individual packaging when caffeine is only present from the use of these foods. Other minor clarifications to labelling requirements were also made to provide more clarity, based on stakeholder feedback, which changed the way that amendments to the Code were expressed, but not the intention.
Some submitters raised concerned about alcoholic drinks containing caffeine not being included in CBA analysis.	Those products were not included in the CBA analysis as it's not expected that any regulatory burden will be imposed on them as a result of the proposed changes. FSANZ indicated that a small number of products are expected to be impacted by the prohibition of guarana extract (except where expressly permitted to be added). FSANZ did not receive alternative estimates to quantify this impact.

7 What is the best option from those considered and how will it be implemented?

7.1 Option 2 is the recommended option

FSANZ's view is that Option 2 is the best option to address the problem outlined above.

This is because Option 2 is likely to have a net benefit, as discussed in section 5.3.

The option also meets the desired outcomes of the proposal. The outcomes of the proposal (as outlined in section 3.1) are to:

- minimise the risk of overconsumption of caffeine (especially for vulnerable people)
- provide a means for FSSF to assist sports people in achieving specific performance goals
- provide adequate information to enable consumers to make an informed choice, and for governments to monitor the market and enforce the Code
- provide an effective regulatory framework within which the food industry can work efficiently.

Maintaining status quo does not achieve the desired outcomes of the proposal. Primarily, it does not address the risks of overconsumption identified in section 1.8. It also doesn't resolve other problems identified.

Option 2 does achieve the desired outcomes of the proposal. It does this by:

- prohibiting the addition of caffeine (and guarana extract) to food, unless permitted, minimising the risk of overconsumption of caffeine in the case of a trend toward greater caffeination of the food supply
- setting a limit for caffeine in FSSF that balances safety and performance goals
- establishing labelling requirements for FSSF and some coffee drinks, to provide consumers with clear and consistent information to make informed choices
- establishing packaging requirements for some FSSF.

7.2 Decision-making process for the proposed changes

The FSANZ Board will make a decision to approve, amend or reject the proposed variations to the Code.

All FSANZ decisions on proposals are notified to Food Ministers (from the Commonwealth, Australian States and Territories and New Zealand) who can, within 60 days of notification from FSANZ, decide to either:

- ask for a review, or
- agree that the standard should become law.

If ministers do not seek a review, the changes are:

- registered as legislative instruments in Australia on the Federal Register of Legislative Instruments and gazetted
- issued as a food standard in New Zealand by the New Zealand Minister for Food Safety.

If a review is requested, FSANZ will review the proposal. Review requests must be finalised within three months, unless an extension is granted by the Food Ministers. The proposal would come back to the Board to decide to either:

- reaffirm its decision (with or without changes to the proposal), or
- withdraw its approval (resulting in no change to the Code).

Reviewed decisions are returned to Food Ministers for further consideration. Food Ministers can accept, amend or reject the draft standard.

7.3 How will the proposed changes be implemented

It is expected that this proposal will follow standard implementation procedures for changes to the Code, which are described in this section.

7.3.1 Implementation process

It is expected that this proposal will follow the standard implementation process for the food regulatory system.

Within the food regulation system, FSANZ develops the standards. If the draft variation is approved, implementation and enforcement of the draft variation to the Code would be the responsibility of the Australian states and territory and New Zealand food regulation agencies.

Food enforcement agencies work together through the Implementation Subcommittee for Food Regulation (ISFR). ISFR helps to ensure the implementation and enforcement of food standards is consistent across Australia and New Zealand.

While ISFR aim to implement standards consistently, member jurisdictions retain the authority to make and implement decisions about compliance and enforcement issues in their jurisdiction.

FSANZ supports implementation by consulting on proposed changes to the Code, providing support to jurisdictions to coordinate implementation across jurisdictions, and providing support materials to businesses and consumers.

Compliance is enforced and non-compliance is addressed under each jurisdictions' Food Act[32]. Those Food Acts and related legislation also specify penalties for non-compliance.

Various government agencies monitor and enforce food regulation, which each jurisdiction having different arrangements for enforcement. Within the food system, these government agencies include the:

- Ministry for Primary Industries, public health units and territorial authorities in New Zealand
- state and territory agencies in Australia and local government authorities
- Department of Agriculture, Fisheries and Forestry in Australia – in relation to food imports.

Verifying compliance forms part of routine audit or inspection activity by government officers. Typically, government take a risk-based approach to these activities. Additionally, jurisdictions follow-up on specific complaints by individuals or organisations.

The food regulation system follows the home jurisdiction rule to coordinate responses to food standards matters across borders to prevent duplication and facilitate communication.

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[32] *A list of the relevant Australian and New Zealand food acts and regulations can be found on the FSANZ website*

The home jurisdiction is the state or territory in which a food business is based or, in the case of a national chain, where the home company's head office is located.

The home jurisdiction is responsible for investigating potential breaches of food legislation including complaints and undertaking any necessary compliance or enforcement action in relation to the business. Typically, the home jurisdiction will also take a lead role in coordinating any investigation that involves other state and territory enforcement agencies.

7.3.2 Implementation challenges

FSANZ does not expect there to be any significant challenges to successfully implementing the changes to the standards. This is because changes to the Code are made frequently, therefore the food regulatory system is well equipped to manage changes.

7.3.3 Transition period for implementation

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

The two-year transition period balances minimising costs for businesses, particularly for smaller businesses where costs may be disproportionally higher, with not unduly delaying the amendments.

A transition period greater than two years may unnecessarily prolong the implementation of the proposed amendments with a resulting cost to public health and safety.

FSANZ considers the caffeine concentration limits put in place through P1054 manage the risk to the Australia and New Zealand population from highly concentrated forms of caffeine during this transition period.

FSANZ considers a transition period of two years is appropriate given required labelling and compositional changes. This change is commensurate with the transition periods for similar applications and proposals requiring compositional and label changes (for example P1030 – Composition and labelling of electrolyte drinks) and recognises the relatively long shelf-life of FSSF.

At the 1st CFS, industry stakeholders suggested that labelling changes and reformulation could take between 6 and 36 months. At the 2nd CFS, FSANZ proposed the two-year transition period. No industry stakeholders commented on the transition period and some government stakeholders supported the length of the transition period.

8 How will the chosen option be evaluated?

Across Australia and New Zealand's food regulatory system, multiple agencies have responsibility for actively monitoring and evaluating food standards including FSANZ and other Commonwealth agencies and the jurisdictions.

Under the food regulatory system, the Commonwealth and jurisdictions develop the policy principles against which FSANZ consider when developing food standards. This structure also provides for reviewing the outcomes of the standards against their policy principles.

Agencies with responsibility for food policy or implementation or standards development could act individually or in concert to evaluate and/or monitor the standards. Such monitoring and evaluation can be coordinated either through the Food Regulation Standing Committee or the Implementation Subcommittee for Food Regulation.

Objectives of an evaluation for P1056 could focus on whether the standards developed:

- prevented caffeine being added to food, where specific permissions do not exist
- prevented (supported by other measures) serious harm to consumers
- were enforceable by jurisdictions, and clear to industry
- remain up to date with market developments
- remain up to date with scientific developments (for example, understanding of caffeine risks, or benefits)

A range of evidence could be used to evaluate the standard.

As dietary exposure data is updated, it could be used to examine whether the risk management approaches adopted remain appropriate for the amount of caffeine consumed by the population changes over time.

Market data can be used to monitor products on the market. Market data is available from a number of sources across the food regulatory system and beyond. FSANZ will continue to update the Branded Food Database, which (as shown by this DRIS) is able to monitor product labels and composition.

Studies on consumer behaviour could also be used to evaluate the standard. The social science literature review (SD 3) could be updated in future to consider new studies. Another potential source of data related to consumer behaviour is FSANZ's Consumer Insights Tracker, which can inform FSANZ of emerging issues of importance to consumers and could be used to target consumer education or guidance).

The safety assessment (SD 1), which was a literature review of available scientific studies could be updated in future to consider new studies on the safety of caffeine.

Individual cases and events can also provide information to evaluate the standard. For example, P1054 was created in response to a death.

References

Supporting documents to the Approval Report

This document references the following supporting documents (SD) to the Approval Report:

SD1 Safety assessment of caffeine

SD2 Dietary intake assessment

SD3 Social science literature review

SD4 Assessment of caffeine and sports performance

To review the references refer to the P1056 page on the FSANZ website.

All other references are listed below.

Other references

ABS 2022, *Hypertension and high measured blood pressure*, ABS, viewed 16 January 2026, https://www.abs.gov.au/statistics/health/health-conditions-and-risks/hypertension-and-high-measured-blood-pressure/latest-release

ABC (2023) Submission – Proposal P1056 – Caffeine Review – 1st Call for Submissions. Australian Beverages Council, Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/p1056

ABS (2024) Employee Earnings and Hours, Australia, May 2023. Australian Bureau of Statistics, Canberra. Available online at: https://www.abs.gov.au/statistics/labour/earnings-and-working-conditions/employee-earnings-and-hours-australia

ABS (2025) Wage Price Index, Australia, June 2025. Australian Bureau of Statistics, Canberra. Available online at: https://www.abs.gov.au/statistics/economy/price-indexes-and-inflation/wage-price-index-australia/jun-2025

ABS (2026) Population clock and pyramid, Australia, January 2026. Australian Bureau of Statistics, Canberra. Available online at: https://www.abs.gov.au/statistics/people/population/population-clock-pyramidAFGC (2023) Submission – Proposal P1056 – Caffeine Review – 1st Call for Submissions. Australian Food & Grocery Council, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/p1056

AIHW (2024) *Australian Burden of Disease Study 2024 – Summary*. Australian Institute of Health and Welfare, Available online at: https://www.aihw.gov.au/reports/burden-of-disease/australian-burden-of-disease-study-2024/contents/summary

AIS (2023) Submission – Proposal P1056 – Caffeine Review – 1st Call for Submissions. Australian Institute of Sport, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/p1056

AIS. (2025). "Nutrition – Supplements – Group A." Retrieved 15/10, 2025, from https://www.ausport.gov.au/ais/nutrition/supplements/group_a.

ALDI (2023) Submission – Proposal P1056 – Caffeine Review – 1st Call for Submissions. ALDI Australia, Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/p1056

Atkins, E.R., Nguyen, L.H., Chatterton, M.L., Schlaich, M., Schutte, A.E. and Rodgers, A. (2024), The cost of treating hypertension in Australia, 2012–22: an economic analysis. Med J Aust, 221: 612-616. https://doi.org/10.5694/mja2.52522ATP (2023) Submission – Proposal P1056 – Caffeine Review – 1st Call for Submissions. ATP Science, Meadowbrook. Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/p1056

Australian Government (2007) Best Practice Regulation Handbook. Canberra.

CIE (2002). Evaluating benefits and costs of food regulation: a scoping study. Centre for International Economics. Canberra & Sydney.

CIE (2008). Measuring consumer costs and benefits in Commonwealth and State and Territory Governments RISs. Centre for International Economics. Canberra & Sydney.

Chapple, C.I., Russell, C.G., Burnett, A.J. & Woods, J.L. (2023) *Sports foods are not all they shake up to be: An audit of formulated supplementary sports food products and packaging in Australian retail environments*. Frontiers in Nutrition, 10, 2049

Chapple, C.I., Burnett, A.J., Woods, J.L. & Russell, C.G. (2024) *A Cross-Sectional Study of Sports Food Consumption Patterns, Experiences, and Perceptions amongst Non-Athletes in Australia*. Nutrients, 16, 1101CMA (2025) CMA submission: P1056 - Caffeine review 2nd Call for Submissions. Complementary Medicines Australia, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/p1056

CMA (UK) (2023) Competition assessment: guidelines for policymakers. Competition and Markets Authority (United Kingdom), London. Available online at: https://www.gov.uk/government/publications/competition-impact-assessment-guidelines-for-policymakers

EFSA (2015) Scientific opinion on the safety of caffeine. European Food Safety Authority, Parma, Italy. Available online at: https://www.efsa.europa.eu/en/efsajournal/pub/4102

Euromonitor International (2023a) *Sports Nutrition in Australia*. Available at: <https://www-portal-euromonitor-com.ezproxy-b.deakin.edu.au/Analysis/Tab> (Accessed 17 December 2023).

Euromonitor International (2023b) *Sports Nutrition in World*. Available at: <https://www-portal-euromonitor-com.ezproxy-f.deakin.edu.au/Analysis/Tab> (Accessed 18 September 2023).

Euromonitor (2024a) Passport – Sports Nutrition in Australia. Euromonitor International, Available online at: https://www.euromonitor.com/sports-nutrition-in-australia/report

Euromonitor (2024b) Passport – Sports Nutrition in New Zealand. Euromonitor International, Available online at: https://www.euromonitor.com/sports-nutrition-in-new-zealand/report

Frucor Suntory (2023) Submission – Proposal P1056 – Caffeine Review – 1st Call for Submissions. Frucor Suntory, Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/p1056

FSANZ (1999) Proposal P167 – Review of Nutrition Labelling – Full Assessment Report. Food Standards Australia New Zealand, Canberra. Available online at: https://www.foodstandards.gov.au/publications/Review-of-Nutrition-Labelling-Full-Assessment-Report-Proposal-P167-%281999%29

FSANZ (2000) Safety aspects of dietary caffeine – Report from the Expert Working Group. Food Standards Australia New Zealand, Canberra. Available online at: https://www.foodstandards.gov.au/publications/Safety-aspects-of-dietary-caffeine

FSANZ (2013) Sports Foods Consumption in Australia and New Zealand. Food Standards Australia New Zealand, Canberra. Available online at: https://www.foodstandards.gov.au/publications/Sports-Foods-Consumption-in-Australia-and-New-Zealand

FSANZ (2015) Proposal P1024 – Revision of the Regulation of Nutritive Substances & Novel Foods – Call for submissions (4 December 2015). Food Standards Australia New Zealand, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/P1024

FSANZ (2020a) Urgent Proposal P1054 – Amendment of the approved variation report. Food Standards Australia New Zealand, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/P1054

FSANZ (2020b) Urgent Proposal P1054 – Pure and highly concentrated caffeine products – Call for submissions – Assessment of the Approved Variation. Food Standards Australia New Zealand, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/P1054

FSANZ (2022) Proposal P1028 – Infant formula – 1st Call for submissions – Supporting Document 3 (SD3): Labelling for provision of information – Attachment to SD3 - Consumer research on infant formula labelling. Food Standards Australia New Zealand, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/P1028

FSANZ (2024a) Consumer Insights Tracker 2023: Technical Report. Food Standards Australia New Zealand, Canberra. Available online at: https://www.foodstandards.gov.au/science-data/social-science/consumer-insights-tracker

FSANZ (2024b) Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (2nd Edition). Food Standards Australia New Zealand, Canberra. Available online at: https://www.foodstandards.gov.au/publications/principles-and-practices-of-dietary-exposure-assessment

FSANZ (2025) Consumer Insights Tracker 2024: Technical Report. Food Standards Australia New Zealand, Canberra. Available online at: https://www.foodstandards.gov.au/science-data/social-science/consumer-insights-tracker

Gootenberg P (2023) Guaraná: How Brazil Embraced the World's Most Caffeine-Rich Plant. Hispanic American Historical Review, 103(4):699-700.

doi:10.1215/00182168-10798146

IBISWorld (2025) Vitamin and Supplement Manufacturing in Australia. IBISWorld, Available online at: https://www.ibisworld.com/australia/industry/vitamin-and-supplement-manufacturing/5417/

Keast RSJ, Sayompark D, Sacks G, Swinburn BA, Riddell LJ (2011) The influence of caffeine on energy content of sugar-sweetened beverages: 'the caffeine–calorie effect'. European Journal of Clinical Nutrition, 65(12):1338-1344.

doi:10.1038/ejcn.2011.123

KPMG (2020) Sports Industry Economic Analysis – Exploring the size and growth potential of the Sport Industry in Australia – Final Report. KPMG, Available online at: https://www.infrastructure.gov.au/department/media/publications/sports-industry-economic-analysis

Maughan RJ, Burke LM, Dvorak J, Larson-Meyer DE, Peeling P, Phillips SM, Rawson ES, Walsh NP, Garthe I, Geyer H, Meeusen R, van Loon L, Shirreffs SM, Spriet LL, Stuart M, Vernec A, Currell K, Ali VM, Budgett RGM, Ljungqvist A, Mountjoy M, Pitsiladis Y, Soligard T, Erdener U, Engebretsen L (2018) IOC Consensus Statement: Dietary Supplements and the High-Performance Athlete. Int J Sport Nutr Exerc Metab, 28(2):104-125.

doi:10.1123/ijsnem.2018-0020

NSWPIC (2023) Submission – Proposal P1056 – Caffeine Review – 1st Call for Submissions. NSW Poisons Information Centre, Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/p1056

NZFGC (2023) Submission – Proposal P1056 – Caffeine Review – 1st Call for Submissions. New Zealand Food and Grocery Council, Wellington. Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/p1056

NZFGC (2025) Submission – Proposal P1056 – Caffeine Review – 2nd Call for Submissions. New Zealand Food and Grocery Council, Wellington. Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/p1056

NZFS (2023) Submission – Proposal P1056 – Caffeine Review – 1st Call for Submissions. New Zealand Food Safety, Wellington. Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/p1056OIA (2023a) Guidance - Cost Benefit Analysis. Office of Impact Analysis, Canberra. Available online at: https://oia.pmc.gov.au/resources/guidance-assessing-impacts/cost-benefit-analysis

OIA (2023b) Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies. Office of Impact Analysis, Canberra. Available online at: https://oia.pmc.gov.au/resources/guidance-impact-analysis/regulatory-impact-analysis-guide-ministers-meetings-and-national

OIA (2024) Guidance note – Regulatory Burden Measurement Framework. Office of Best Practice Regulation, Canberra. Available online at: https://oia.pmc.gov.au/resources/guidance-assessing-impacts/regulatory-burden-measurement-framework

OMB (2023) Circular No. A-4 (November 9, 2023) – Regulatory Analysis. Office of Management and Budget, Washington, D.C. Available online at: https://bidenwhitehouse.archives.gov/wp-content/uploads/2023/11/CircularA-4.pdf

SDA (2023) Submission – Proposal P1056 – Caffeine Review – 1st Call for Submissions. Sports Dietitians Australia, South Melbourne. Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/p1056

SleepFit / Deloitte Access Economics (2023) *Asleep on the Job: Costs of Inadequate Sleep in Australia*. Available online at: https://cdn.prod.website-files.com/64b4b7e38dda973fdbb7faf2/65025d4dbfb53143f206f321_Asleep%20on%20the%20Job-%20Costs%20of%20Inadequate%20Sleep%20in%20Australia.pdf

Sweeney K & Shui H (2016) *The economic cost of serious mental illness and comorbidities in Australia and New Zealand*. Report prepared for the Royal Australian and New Zealand College of Psychiatrists and the Australian Health Policy Collaboration by the Victoria Institute of Strategic Economic Studies. Royal Australian and New Zealand College of Psychiatrists, Melbourne.

Stats NZ (2026) National populations projections, New Zealand, January 2025. Stats NZ Tatauranga Aotearoa. Availabel at: National population projections, by age and sex, 2024(base)-2078

TGA (2020) Proposal to clarify that certain sports supplements should be regulated as therapeutic goods – Regulation Impact Statement for the Minister for Health. Therapeutic Goods Administration, Canberra. Available online at: https://www.tga.gov.au/resources/publication/corporate-reports/regulation-impact-statement-proposal-clarify-certain-sports-supplements-should-be-regulated-therapeutic-goods

TGA (2025) TGA response to FSANZ P1056 2nd Call for Submissions – Caffeine Review. Theraputic Goods Administration, Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/p1056

TNS (2004). Consumer research on the need for consistency in nutrition information panels. TNS Social Research. Canberra.

USFDA (2018) Guidance for Industry: Highly Concentrated Caffeine in Dietary Supplements. United States Food and Drug Administration. United States Food and Drug Administration, Available online at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-highly-concentrated-caffeine-dietary-supplements

Wham C, Rowe K, Ali A, Rutherford-Markwick K (2017) Influences of caffeine consumption among adult New Zealanders: A qualitative study. Journal of Caffeine Research, 7(4):142-150.doi:10.1089/jcr.2017.0020

Appendix A - Options considered, but not included in the final proposal

FSANZ has considered a number of potential amendments to the Code, which were ultimately not adopted as part of the proposal. These potential amendments and why they were not adopted as part of the proposal are summarised in the table below.

For more information refer to the 1st and 2nd CFS, and Approval Report.

Option or amendment	Reason not adopted
Option for a standalone education campaign on caffeine safety (non-regulatory option)	Option put forward at 1st CFS. This option was not the preferred option for FSANZ as it was considered insufficient to address the risks to vulnerable populations identified by the risk assessment. Submitters to the 1st CFS supported regulation rather than a non-regulatory approach, to address the serious health consequences of inadvertent or excessive caffeine intake, to increase regulatory clarity and to protect vulnerable sub-populations. Consumer education materials on the risks of pure and highly concentrated caffeine products are already available on the FSANZ website[33] and these would be updated to ensure consistency with the new requirements for caffeine in food, if approved. Based on feedback from submissions to P1056 public consultation and ongoing discussions with jurisdictions, FSANZ will consider the best way to approach consumer education on caffeine in the food supply. FSANZ anticipates working cooperatively with these organisations to ensure consistency of information and to maximise the effectiveness of available resources.
Removing prohibition of the retail sale of any food in which caffeine is present in a concentration of 1% (liquids) or 5% (non-liquids)	Option put forward at 1st CFS, which has been partially adopted for the final proposal. After considering submissions, reviewing the market scan (SD5), and reconsidering the risk posed by impacted products, the concentration limits have been retained for liquid (1%) and powdered (5%) FSSF only. In addition, a new requirement was introduced at the 2nd CFS to require individual servings of ready to eat solid and semi-solid caffeinated FSSF that are in a multi-pack containing more than 200 mg of caffeine in total to be separately packaged.

[33] See the Caffeine consumer information page on the FSANZ website. Consumer education materials are also provided by jurisdictional governments, as well as by health authorities at all levels of government

Option or amendment	Reason not adopted
Minimum level of caffeine in caffeinated FSSF	Option considered as part of the 1st CFS but not adopted. This is because there can be inter-individual differences in caffeine metabolism and sensitivity, and setting a minimum effective amount is not appropriate.
Allowing health claims to be made about caffeine in FSSF (for example, claims relating to the performance benefits of consuming caffeine)	Option considered as part of the 1st CFS but not adopted. The regulation of health claims for FSSF is being reviewed by FSANZ under Proposal P1010 – Formulated supplementary sports foods.
Use the existing warning label for FSSF, for caffeinated products: "*Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision*"	Option put forward at 1st CFS. The warning statement has been updated to be the same as that for the existing warning statement, with the addition of breastfeeding women. This approach takes into account concerns raised by submitters, evidence that a portion of caffeine circulating in the bloodstream enters breast milk, and that there is insufficient data to establish a health-based guidance value for breastfed infants for caffeine consumed via breastmilk.
New labelling provisions for caffeine containing FSSF apply to all caffeinated FSSF, regardless of amount or source	Option put forward at 1st CFS and maintained at 2nd CFS. Following stakeholder concerns about the proposal applying to FSSF with negligible amounts of caffeine, the draft variation was amended after the 2nd CFS to provide an exemption where the source of caffeine is limited to any or all of the following foods: cocoa, chocolate or decaffeinated tea and decaffeinated coffee.
No restrictions related to naturally occurring caffeine being sold as a food or added to a food	FSANZ did not propose such requirements as part of the proposal at 1st CFS or 2nd CFS. Following stakeholder concerns, the proposal was amended after the 2nd CFS to specifically prohibit guarana extract (the primary 'caffeine-rich plant extract') being sold as a food for retail sale or added to foods (unless caffeine is permitted to be added to that food). Stakeholders were concerned that without this specific prohibition, the intent of the proposal may not have been achieved.

Option or amendment	Reason not adopted
No specific caffeine-related labelling requirements for non-sports food products that contain caffeine by natural occurrence	FSANZ did not propose such requirements as part of the proposal at 1st CFS or 2nd CFS. Stakeholders were concerned about beverages containing high amounts of naturally occurring caffeine from coffee (e.g. ice coffee milk drinks). The draft variation was amended after the 2nd CFS to require any packaged beverage containing coffee and 200 mg or more caffeine per serve to declare the caffeine content and carry a warning statement (but only for products required to display a NIP).

Appendix B - Key stakeholder issues raised at the 2nd CFS

Table below summarises the amendments made to the draft variation to the Code that was presented to stakeholders at the 2nd CFS.

Minor clarifications were also made, based on stakeholder feedback, which changed the way that amendments to the Code were expressed, but not the intention

Key issue	How feedback has been incorporated
Submitters raised issues with how the proposal would apply to plant-extracts which can be highly caffeinated, for example guarana extract. This related to extracts sold as a food themselves or added as an ingredient to general foods. Many were of the view that the drafting presented did not effectively control the risks related to these extracts, due to a lack of regulatory clarity.	In response to these concerns, FSANZ made a number of amendments to the drafting specifically for guarana extract. In response, FSANZ amended the drafting to: • prohibit the retail sale of guarana extract as a food • clarified in the drafting (through new provisions and examples) that the prohibition on adding caffeine would apply to guarana extract. clarified in the drafting (by way of an example) when an ingredient is considered to be naturally occurring and thus exempt from the prohibition Other plant extracts that may be high in caffeine were not included in the amended drafting, in FSANZ's view these may be classified as unapproved novel foods and therefore require explicit permission under the Code.
Submitters raised concerns about coffee containing beverages that are high in caffeine, which were not impacted by the proposal. Examples were provided of iced coffee products on the market that had 250 mg to 300 mg of caffeine per serve.	In response to these concerns, FSANZ amended the proposal to include new labelling requirements for coffee containing beverages with more than 200 mg of caffeine per serve. FSANZ did not include a compositional limit for these beverages, as this would not be proportionate to the level of risk presented by coffee beverages and would be difficult to enforce.
Submitters noted that the requirements for FSSF apply to all FSSF containing caffeine, regardless of the level of risk.	In response to these concerns, FSANZ amended the proposal to provide an exemption from the new labelling requirements where caffeine is present in FSSF only from chocolate, cocoa, decaffeinated tea and/or decaffeinated coffee.

Key issue	How feedback has been incorporated
For example, some FSSF contain low amounts of naturally occurring caffeine from chocolate or cocoa that is added for flavour.	If caffeine is present from any other source, the exemption does not apply.
Some submitters raised concerns that the requirement for certain caffeinated FSSF to be individually packaged did not sufficiently address the risk posed by these products, particularly for younger children. A small number of submitters suggested the warning statements required on the outer packaging of FSSF should also be displayed on individual portions to avoid inadvertent excessive caffeine consumption.	In response to these concerns, FSANZ amended this element of the proposal to require an advisory statement to the effect of 'contains caffeine' on individual portions subject to individual packaging requirements. The requirement would not apply if the surface area of the label is less than 30 cm^2. FSANZ did not include a requirement to label individual portions with a warning statement, as a warning statement would not specifically mention caffeine (limiting its effectiveness of alerting consumers to the presence of caffeine) and it would be onerous to producers due to the length of the statement and the amount of space it would take up on the label (relative to an advisory statement).

Appendix C– Detailed methodology

This Appendix provides more detail on how figures within this document were calculated, including:

- data collection methods
- assumptions made
- calculation steps.

It is intended to provide a greater level of transparency on the methodology used and to improve stakeholder understanding on how figures were quantified.

The methodology was presented to stakeholders at the 2nd CFS, and stakeholders were invited to comments on the methodology used. No comments were received.

Market scan of caffeinated sports foods

Market scan search method

To determine the number of sports foods containing caffeine impacted by the proposal, FSANZ undertook a desktop survey of products available for sale online.

The data was collected in August 2024 for the 2nd CFS. The underlying data was not updated for the DRIS.

In scope were sports foods:

- with caffeine greater than zero
- for sale in Australia and New Zealand (online or in store).

Products regulated by the *New Zealand Food (Supplemented Food) Standard 2016* were included as impacted products, based on an assumption made for the purposes of this cost and benefit analysis that the proposal would apply in both Australia and New Zealand.

Out of scope were:

- therapeutic goods, which were excluded where the products were:
  - TGA listed products, clearly labelled with an 'L number'
  - in the format of a therapeutic, for example tablets, capsules or pills (where not clearly labelled as a therapeutic)
- products meeting the definition of Formulated Caffeinated Beverages (FCBs)
- products sold direct to consumers from websites outside of Australia or New Zealand.

The search method to find the products was:

1. Access the websites of supplement stores[34], supermarkets[35] and online pharmacies[36]
2. Perform a Google search
3. Perform a subsequent scan of Australian or New Zealand[37] brand websites[38], for all products (or brands) identified by the above steps. All products within a brand website were scanned, unless there were a significant number of products, then products most likely to contain caffeine were scanned (i.e. pre-workout, fat burners).

[34] Two supplement stores were searched in Australia, and two in New Zealand
[35] Two supermarkets were searched in Australia, and two in New Zealand
[36] One major online chemist was searched in Australia and New Zealand
[37] The websites of international brands were not searched, to exclude products that are not made available for sale in Australia or New Zealand.
[38] A scan was also done of a major supplier, based in New Zealand, which supplied a significant number of imported products to Australia and New Zealand

This search method is similar to that used by Noetic, for the TGA (2020). Noetic reported that the three websites used by Noetic and FSANZ represented 80% of market share in Australia at that time.

To ensure the list represented products actually for sale to consumers in Australia and New Zealand, an exclusion method was applied. Products were not included on the list where a product:

- was sold out of all flavours in all stores searched, indicating either:
  - retailers did not intend to restock an imported product
  - manufacturers had discontinued the product
- had no evidence of sale within an Australian or New Zealand website. This was based on:
  - scan of websites, as described above
  - a Google search (for products sold in Australia), top 20 hits
  - searching two supplement websites in New Zealand[39]
- was only found on marketplaces, such as Amazon or eBay[40]
- had insufficient information on the label, for example only a tub with a brand name, with no indication of what the product is, or what it contains.

Sachets were included only where they were sold and not given away as samples.

At consultation for the 1st CFS, some manufacturers provided information on the number of SKU within their product range. This information was compared to the data found, to assist in validating the data.

At the 2nd CFS, the methodology and data were presented to stakeholders for comment. No comments were received.

Limitations of data collection method

Below are the identified limitations of the data collection method. These limitations may result in either underestimations or over estimations of the number of products impacted.

The identified limitations are as follows:

- Judgement was used by a single FSANZ officer to screen products listed on websites based on their name, purpose, and front of pack picture. This may have resulted in some products being incorrectly excluded.
  - For example, products similar in appearance to pre-workout products like BCAAs or creatine, that appeared to be single ingredient products were excluded based on name only and not a review of their ingredients list.

[39] Given the author was in Australia, a Google search would be unlikely provide reliable results on products for sale in New Zealand.
[40] Online marketplaces were excluded due to practical difficulties analysing multiple listings for the one product, across many different products, to determine whether the seller is within scope of the proposal

- Due to a lack of an explicit permission, there is no requirement in Standard 2.9.4 to label the presence of caffeine, and therefore it is likely a small number of caffeine containing products were incorrectly excluded.
- The caffeine content of many products was not clearly identified or totalled, in some cases judgement was used which may have resulted in a small number of products caffeine content being misclassified as under or over 200 mg
- The labels for some products differed between websites, for example on some websites a product was labelled as Australian made, while on another website the same product had a different label that said the product was made in the USA. In these cases, it was assumed the product was made in Australia.
- Key on-product label information was missing for some products. Where this was the case, the following process was followed:
  - search for the product on other websites, to find missing labels
  - search for the product on the brand's website, to find missing labels
  - collect information from the product listing, or listing brand website
  - collect information from other sources – for example a Google search of the company to determine where they manufacture products.
- Whether products should be captured in the data was not always clear. To overcome this, an assumption was made that a product should be included in the data when it is marketed and/or presents in the same way as a sports food. Some examples of this issue were:
  - online listings showing 'clean' labels, containing only marketing information and missing elements of the actual product label like barcodes, warnings, 'made in' information, and type of food (formulated supplementary sports food, listed medicine, or other)
  - only front of pack information presented, the type of food not being listed on the front of pack, and the webpage listing not including this information
  - products in a powdered format labelled as 'formulated caffeinated beverages' (out of scope) that appear to be sports foods (in-scope).

Number of impacted caffeinated sports foods found

Below are some statistics, summarising the data found. SKU is a count of the number of different formats a single product will take, taking into account different flavours and packet sizes and forms.

Number of sports foods found in market scan, by caffeine content

	Over 200 mg per serve	Under 200 mg per serve	Total
Unique products	127	104	232
SKU	719	482	1201

Note: Total is higher due to a small number of products having an unknown total caffeine content

Number of sports foods found in market scan, by country of origin

	Australia	New Zealand	USA	Other
Unique products	100	35	81	16
Proportion	43%	15%	35%	7%

Proportion of impacted products that are out of scope for cost and benefit analysis

The scope of the cost benefit analysis was limited to impacts on consumers, businesses and governments within Australia and New Zealand.

The market scan found that approximately 42% of caffeinated sports foods (on an SKU basis) for sale on Australian and New Zealand websites was made[41] outside of Australia or New Zealand and therefore excluded from the analysis.

Proportion of impacted caffeinated sport food product lines that are discontinued, where brand has another compliant product on the market

FSANZ has assumed that all caffeinated sport food product lines containing over 200 mg of caffeine will be discontinued in the following circumstance:

- a brand has a product that is over 200 mg per serve and therefore exceeds the proposed maximum of 200 mg caffeine per one-day quantity
- the same brand has a product that is under 200 mg per serve
- the products are for the same purpose.

This assumption is made because it is less likely that there will be a return on investment in this circumstance.

FSANZ has estimated that approximately 12% of the SKU on the market will be discontinued in this circumstance.

Calculating the cost of relabelling caffeinated sports foods

Relabel cost – MJA estimated per label cost

FSANZ commissioned research from Marsden Jacob Associates (MJA) on the cost of relabelling products, based on a survey of businesses.

The MJA research presents costs across two dimensions, label type and complexity of change (minor, medium or major change). It is expected that the label changes required for this proposal will be either minor or medium.

The relevant costs for this proposal are outlined in the table below.

[41] Whether products were 'made in' was based on the Australian Made or New Zealand Made logos, which means products 'packed in' Australia or New Zealand are counted as 'made' in either country

Label type	Cost, minor change (per SKU)	Cost, medium change (per SKU)
Adhesive label on container (such as a plastic tub)	A$3,622	A$4,391
Paper based label (such as paper-based sachets and sachet pouches)	A$2,366	A$4,564
Plastic pouch	A$7,558	A$8,461

The costs originally used in the 2nd CFS were updated for inflation, using the Australian Bureau of Statistics Producer Price Index as at September 2025.

In addition, a minor correction was made to the methodology after the 2nd CFS, to remove shrink film from the weighted average, due to a low number of products using this type of packaging.

Relabel cost – scale of label changes

The following table describes how each type of change is characterised.

Scale of change	Scope of change
Minor	Label design – text changes only, no change to layout of label Proofing – not required Package redesign – no change to packaging shape / size
Medium	Label design – changes to text and label layout Proofing – required No change to label shape / size
Major	Label design – major changes to text and label layout and label shape/size Proofing – required

To determine which 'scale' should be used for the costing, FSANZ conducted a convenience sample of 19 Australian or New Zealand product labels (from the market scan) and assessed them against the above criteria. A sample was used because complete labels were not available for all many products.

It was found;

- 15 of the products sampled would require a minor change
  - all 15 would require adjusting the layout of the nutrition information panel (NIP)
  - no other label elements were missing, some text may need adjusting
- 4 of the products sampled would require a medium change
  - all 4 would require significant changes to the NIP to the extent that the layout would change, including to remove nutrition information for two servings
  - no products would require a larger label
- no products would require
- a major change, as all sampled products fit into the minor or medium categories.

Based on these findings, approximately;

- 80% of product relabelling will be at the minor cost
- 20% at medium cost.

The findings have changed slightly from the 2nd CFS, as a result of more complete label images being available to review. The proportion of labels with a minor change has increased from 70% to 80%.

Relabel cost – weighted average cost per label

To take account of the different product types, the following weighted average was used.

	Cost, minor change (per SKU)	Cost, medium change (per SKU)
Weighted average cost of relabelling	A$3,768	A$4,649
Proportion of products in this category	80%	20%

Relabel costs – activity breakdown

The following costs are included in the cost of relabelling.

Activity	Cost, minor change (weighted average, per SKU)	Cost, medium change (weighted average, per SKU)
Administration activities	A$783	A$703
Label redesign	A$1,332	A$2,274
Market testing	A$0	A$92
Develop proof and film/files, engrave plates/cylinders and colour match	A$973	A$945
Review label sample	A$681	A$636
Total, weighted average	**A$3,768**	**A$4,649**

Assumption – all impacted products that would require relabelling to continue being sold

It has been assumed that all impacted products that remain on the market will need to be relabelled. This is based on a review of products on the market, produced in Australia or New Zealand.

The review did not find a single product label that would not require adjustment. It was common for products to only require minor adjustments. Examples of changes required, based on the market scan, are summarised in the table below.

Labelling requirement proposed	Labelling practices of products on the market don't meet the proposed requirements
'Contains caffeine' statement	• Caffeine not declared in low caffeine sport food (for example, protein powders with a small amount of added caffeine designed for 'shredding')
Declaration of total caffeine content from all sources on the label, under sodium	• Caffeine quantity listed in the nutrition information panel, but not under sodium • Caffeine quantity listed in a separate table • Caffeine quantity listed on the front of pack only • Caffeine quantity not totalled, listed separately by contributing ingredient in nutrition panel • Caffeine quantity not directly provided, instead quantity of caffeine containing ingredient listed in nutrition panel
Warning and advisory statements	• Warning and advisory statement provided differs from the P1056 proposed approach

Relabelling cost – final result

The final cost is presented below.

The cost is presented as a range, as there is considerable uncertainty about how businesses will behave in response to the proposal. A range of scenarios has been tested, where no product variants are discontinued, to a scenario where up to half of all product variants are discontinued.

Relabelling products – total cost

	Medium scenario	**Low scenario**	**Conservative scenario**
Proportion of product lines withdrawn	50%	25%	0%
Number of products relabelled	483	725	966
Total estimated relabelling cost	**A$1.9m**	**A$2.9m**	**A$3.8m**

Note that this cost is the for Australian and New Zealand based businesses only.

Calculating reformulation costs

Reformulation costs – per product recipe cost

The cost per product recipe is based on an estimate made by the Noetic group, for the TGA RIS (2020).

Noetic estimated that a complex reformulation of a sports food would take 3,360 minutes (or 56 hours) per reformulation. This was based on interviews with industry stakeholders.

FSANZ has assumed that removing caffeine will be complex. Caffeine impacts on the perception of sweetness (Keast et al. 2011) and therefore when caffeine is removed the amount of sweeteners added needs to be carefully reduced for a product to have the same perceived sweetness level. Failing to make these adjustments would reduce consume acceptance of impacted products.

The cost per hour is summarised in the following table.

Reformulation cost – estimated cost per hour

Cost category	**Cost (per hour)**	**Source**
Labour costs[42] (LC), June 2025 prices *Average hourly wage*	A$65.19[43]	ABS (2024), ABS (2025)
Non-wage labour costs *Overhead costs, on an hourly basis*	$1.75 \times LC$	OIA (2024)

[42] Labour costs for 'professionals' used. Professionals are defined by the ABS – "Professionals perform analytical … tasks through the application of theoretical knowledge and experience in the fields of… engineering, the physical and life science..."

[43] May 2023 data, adjusted using June wage price index

Adjusted labour cost – per hour	**A$114.08**	

The total cost per product line is summarised below.

Reformulation cost – total cost per product

Item	Value	Source
Time required to reformulate product recipe – hours	56	TGA (2020)
Adjusted labour cost – per hour	A$114.08	See above table
Total cost – per product recipe	**A$6,389**	

The costs presented at the 2nd CFS have been updated for inflation, using the wage price index (ABS 2025).

Reformulation costs – proportion of products reformulated

The number of products reformulated is the number of unique product formulations or recipes.

The number of products expected to be reformulated is based on the market scan, adjusted using the same methodology previously described.

However, not all products are over the 200 mg caffeine one-day quantity, therefore only a proportion of products will require reformulation.

The market scan indicated that approximately 60% of products on the market are over the limit.

Reformulation costs – final result and sensitivity analysis

The final estimated reformulation cost is presented in the table below.

The cost is presented as a range, as there is considerable uncertainty about how businesses will behave in response to the proposal. A range of scenarios has been tested, which are summarised in the table below.

Sensitivity analysis of cost of reformulating products

	Medium scenario	Low scenario	Conservative scenario
Proportion of product varieties (flavours, pack sizes) withdrawn[44]	50%	25%	0%
Number of products reformulated	213	320	426

[44] Product lines refer to individual SKU. Each unique variation of a product has a single SKU. For example, one brand of a product can have several different package types, package sizes, and flavors.

Total estimated reformulation cost	A$1.4m	A$2.0m	A$2.7m

Note that this cost is for Australian and New Zealand producers only.

Branded Food Database data

Data from the Branded Food Database (BFD) was used to:

- quantify the number of general foods on the market that contain guarana extract
- quantify the number of coffee drinks with more than 200 mg of caffeine per serve.

The following provides background on the BFG, the methodology used to quantify the above and limitations of the estimate.

Data was collected from the BFD in September and October 2025.

About the Branded Food Database

The BFD contains product information for over 26,000 unique branded products available in the Australian retail market.

The data used in this analysis was sourced directly from brand owners and through in-store collections conducted by FSANZ across Coles, Woolworths and Aldi stores in the ACT from October to mid-November 2024. This includes 24,240 products across a wide range of food categories.

Methodology used to identify products impacted

Coffee drinks impacted by the proposal

To identify coffee drink products impacted by the proposal, a search of ingredients lists in the BFD was undertaken. The following search terms were used

- Coffee powder
- Coffee extract
- Liquid coffee
- Caffeine.

Products that were not beverages were filtered out. Products were then manually filtered to remove products that would not be impacted by the proposal. This included reviewing products labels to remove products with less than 200 mg per serve.

The list of products from the BFD was supplemented by a basic search of:

- Brand websites, for products found on the BFD
- Two supermarket websites in Australia and New Zealand
- A Google search, limited to the first 30 results.

The supplemental search found some brands had an extended range that was not captured in the BFD, a small number of brands and products not found in the BFD, and a small number of products sold in New Zealand which is out of scope for the BFD.

Guarana exact in general foods

To identify products with guarana extract impacted by the proposal, a search of ingredients lists was undertaken. The following search terms were used:

- Guarana
- Guarana powder
- Guarana seed
- Guarana extract.

Products were then manually filtered to remove products that would not be impacted by the proposal, including energy drinks and sports foods.

Limitations of the BFD

The data in the BFD provides a comprehensive snapshot of products sold in the Australian retail market at a point in time.

It does not capture data from all retailers and therefore will not capture data for all products available to Australian consumers.

Data currency and accuracy is also dependent on the accurate provision and entry of data. Annual audits are undertaken to ensure it is as accurate and reflective of the current food supply as possible.

Calculating the cost of relabelling coffee beverages

The cost of relabelling impacted coffee is based on the number of products impacted multiplied by the cost of relabelling.

Based on the product search (see above), FSANZ has estimated that less than 25 coffee beverages would be impacted in both Australia and New Zealand.

The cost per product is expected to be similar to the cost to relabel impacted sports foods. Therefore, the same weighted average cost has been used, which is between A$3,768 (minor change) to A$4,649 (major change).

Based on these figures, FSANZ estimates the total cost of relabelling impacted coffee beverages would be less than A$0.1m. This is a one-off cost.

Calculating the break-even analysis

The break-even analysis was calculated using a model with the following parameters:

- 10 year time period, based on standard assumptions that regulations have a 10 year life (OIA 2024)
- all costs occur in year 0
- benefits occur over 10 years
- a discount rate of 7%, based on OIA requirements for cost and benefit analysis (OIA 2023a)
- the number of consumers each year is based on:
  - ABS and Stats NZ projections of the adult (+18) population
  - the proportion of consumers who consume pre-workout products once a day or more than once a day, based on the 2024 FSANZ Consumer Insights Tracker (FSANZ 2025).

The number of daily pre-workout users has been selected as a proxy for the proportion of consumers consuming caffeinated sports foods daily. The 2024 Consumer Insights Tracker estimated that 5.3% of consumers in Australia and New Zealand consume pre-workout products daily or more than once a day (FSANZ 2025).

A growth rate was not applied to the proportion of consumers consuming caffeinated sports foods, due to difficulties in reliably forecasting this over ten years, which means that the break-even amount may be lower than estimated

With the above parameters, a ‘goal seek’ analysis was used to find the benefit per adult consumer of FSSF per year required for the total benefits to equal costs, factoring in the change in population numbers over the ten year period and a discount rate of 7%.

Population data (all people over 18)

Year	AUS	NZ	Total
2030	23,696,767	4,446,810	28,143,577
2031	24,073,682	4,506,820	28,580,502
2032	24,435,193	4,564,870	29,000,063
2033	24,790,691	4,622,680	29,413,371
2034	25,146,265	4,678,790	29,825,055
2035	25,490,671	4,734,670	30,225,341
2036	25,826,654	4,788,940	30,615,594
2037	26,158,408	4,842,740	31,001,148
2038	26,481,225	4,894,900	31,376,125
2039	26,803,788	4,946,800	31,750,588
2040	27,129,106	4,997,830	32,126,936

Percentage of consumers consuming caffeinated sports foods daily

Consumption frequency %		
More than once a day	**Once a day**	**Total**
1.1	4.2	5.3

Number of daily pre-workout consumers

Year	AUS	NZ	Total
2030	1,255,929	235,681	1,491,610
2031	1,275,905	238,861	1,514,767
2032	1,295,065	241,938	1,537,003
2033	1,313,907	245,002	1,558,909
2034	1,332,752	247,976	1,580,728
2035	1,351,006	250,938	1,601,943
2036	1,368,813	253,814	1,622,626
2037	1,386,396	256,665	1,643,061
2038	1,403,505	259,430	1,662,935
2039	1,420,601	262,180	1,682,781
2040	1,437,843	264,885	1,702,728

Cohort benefits - break even on minimum cost

Year	AUS	NZ	Total
2030	329,338	61,802	391,140
2031	334,576	62,636	397,212
2032	339,601	63,443	403,043
2033	344,541	64,246	408,787
2034	349,483	65,026	414,509
2035	354,270	65,803	420,072
2036	358,939	66,557	425,496
2037	363,550	67,304	430,854
2038	368,036	68,029	436,066
2039	372,519	68,751	441,270
2040	377,041	69,460	446,501

Cohort benefits - break even on maximum cost

Year	AUS	NZ	Total
2030	652,852	122,511	775,363
2031	663,237	124,164	787,401
2032	673,196	125,763	798,960
2033	682,990	127,356	810,346
2034	692,787	128,902	821,688
2035	702,275	130,441	832,716
2036	711,531	131,937	843,468
2037	720,671	133,419	854,090
2038	729,565	134,856	864,421
2039	738,452	136,286	874,737
2040	747,414	137,692	885,106

Break even model

Use Goal Seek function - set total discounted net benefits to zero, by modifying benefit per consumer cell

Benefit per consumer	$ 0.26	<- *Goal seek target*

Min cost of implementation						
Year (no.)	**Year**	**Benefits**	**Costs**	**Net benefits**	**Discount factor**	**Discounted net benefits**
0	2030	$391,140	$3,336,459	-$2,945,319	1	-$2,945,319
1	2031	$397,212	$0	$397,212	0.93	$371,226
2	2032	$403,043	$0	$403,043	0.87	$352,034
3	2033	$408,787	$0	$408,787	0.82	$333,692
4	2034	$414,509	$0	$414,509	0.76	$316,227
5	2035	$420,072	$0	$420,072	0.71	$299,506
6	2036	$425,496	$0	$425,496	0.67	$283,526

Min cost of implementation						
Year (no.)	**Year**	**Benefits**	**Costs**	**Net benefits**	**Discount factor**	**Discounted net benefits**
7	2037	$430,854	$0	$430,854	0.62	$268,314
8	2038	$436,066	$0	$436,066	0.58	$253,794
9	2039	$441,270	$0	$441,270	0.54	$240,022
10	2040	$446,501	$0	$446,501	0.51	$226,978
					Total	$0

Benefit per consumer	$0.52	*<- Goal seek target*

Max cost of implementation						
Year (no.)	**Year**	**Benefits**	**Costs**	**Net benefits**	**Discount factor**	**Discounted net benefits**
0	2030	$775,363	$6,613,922	-$5,838,558	1	-$5,838,558
1	2031	$787,401	$0	$787,401	0.93	$735,889
2	2032	$798,960	$0	$798,960	0.87	$697,842
3	2033	$810,346	$0	$810,346	0.82	$661,484
4	2034	$821,688	$0	$821,688	0.76	$626,862
5	2035	$832,716	$0	$832,716	0.71	$593,715
6	2036	$843,468	$0	$843,468	0.67	$562,038
7	2037	$854,090	$0	$854,090	0.62	$531,884
8	2038	$864,421	$0	$864,421	0.58	$503,101
9	2039	$874,737	$0	$874,737	0.54	$475,799
10	2040	$885,106	$0	$885,106	0.51	$449,943
					Total	$0

Average discounted net benefits per year over 10 years

Year (no.)	Year	Min discounted net benefits	Max discounted next benefits
1	2031	$371,226	$735,889
2	2032	$352,034	$697,842
3	2033	$333,692	$661,484
4	2034	$316,227	$626,862
5	2035	$299,506	$593,715
6	2036	$283,526	$562,038
7	2037	$268,314	$531,884
8	2038	$253,794	$503,101
9	2039	$240,022	$475,799
10	2040	$226,978	$449,943
Average discounted net benefit per year		$294,532	$583,856