

Pure and highly concentrated caffeine products

FSANZ review August 2019



30 August 2019

The Hon Richard Colbeck
Minister for Aged Care and Senior Australians
Minister for Youth and Sport
Parliament House
CANBERRA ACT 2600

The Hon Greg Hunt
Minister for Health
Parliament House
CANBERRA ACT 2600

Dear Ministers

On 10 July 2019 you requested FSANZ consider and provide formal advice regarding the safety of caffeine powders and high caffeine content products, including current regulations and permissions for use, the need for appropriate warning labels and preliminary recommendations for strengthening regulations and consumer warnings.

This review follows the tragic death of Lachlan Foote in January 2018 from caffeine toxicity. I wish to acknowledge Lachlan, his family and friends for whom this report was initiated. I extend my deepest condolences.

The report sets out:

- A summary of current regulations and permissions for use of caffeine in the Australia New Zealand Food Standards Code (the Code)
- Identified high risk areas where regulation should be strengthened
- Recommendations

In preparing this report, FSANZ received willing and valuable assistance from numerous sources including the Therapeutic Goods Administration, the Department of Health, the Department of Agriculture, State and Territory colleagues, New Zealand Ministry for Primary Industries and New Zealand's Medicines and Medical Devices Safety Authority.

Their contribution is gratefully acknowledged.

Yours sincerely



Mark Booth
CEO, Food Standards Australia New Zealand

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Executive summary

In July 2019, the Minister for Aged Care and Senior Australians, the Hon Richard Colbeck and the Minister for Health, the Hon Greg Hunt, requested Food Standards Australia New Zealand (FSANZ) provide information about current caffeine permissions in the Australia New Zealand Food Standards Code (the Code) and prepare preliminary recommendations for strengthening regulations and consumer warnings in relation to caffeine powder and high caffeine content products.

This request was in response to the death of a young man in New South Wales (NSW), Mr Lachlan Foote, whose death was attributed to acute caffeine toxicity associated with the consumption of a caffeine powder (Appendix A).

The NSW State Coroner has also requested FSANZ provide a copy of this report for input into their report and findings into Mr Foote's death. The Coroner's report will invariably provide further information that should be considered in addition to this report.

FSANZ found that a significant risk differential exists between pure caffeine powders and high caffeine content products.

Death has been reported after a single 3 g dose of caffeine. The European Food Safety Authority (EFSA) recommend a maximum daily limit of 400 mg of caffeine per day unless pregnant; if pregnant the maximum is 200 mg. EFSA also recommend a maximum limit of 200 mg per serve. Pure caffeine products can have the maximum 200 mg dose in 1/16th of a teaspoon, with a potentially fatal dose, and the equivalent of 25 - 50 cups of coffee, in one teaspoon.

The fact that a miniscule amount of caffeine powder may result in a lethal quantity, often with the average safe quantity not able to be accurately measured on standard kitchen scales, causes alarm.

Caffeine as an ingredient in other foods does not pose the same level of risk given maximum concentrations may already be prescribed in the Code (cola drinks and energy drinks) or have a much lower concentration (sports foods) than in the same amount of a highly purified form therefore the health effects are likely to be less severe.

The existing food regulation system within Australia is complex, involving all levels of Australian and New Zealand governments. Responsibilities to manage food safety are spread across government agencies and states and territories.

Due to this complexity, and to holistically understand the impact of any regulatory and non-regulatory measure, FSANZ established a Working Group which included food regulatory authorities from the Australian Commonwealth, the Australian States and Territories, New Zealand's Ministry for Primary Industries, and New Zealand's Medicines and Medical Devices Safety Authority.

The Working Group agreed the availability of pure caffeine for retail sale poses an unacceptably high risk and should be considered urgently and separately to products with high caffeine content. FSANZ recommends that pure caffeine be banned from retail sale.

The Working Group agreed that a consumer education campaign, released in conjunction with the retail sale ban (if adopted), would complement the legislative change, increase

awareness of the risks associated with pure caffeine, and increase awareness of the risks associated with importing pure powders over the internet.

Regarding high caffeine content products (e.g. sports and dietary supplements), the Working Group noted a lack of clarity in the Code for permissions to use caffeine in food and suggested a maximum level of caffeine should be considered for inclusion in the Code. Work already underway through the review into Formulated Supplementary Sports Foods, will consider the maximum permitted levels of caffeine and derivatives, and is expected to form a strong basis to extend to other high caffeine content products.

Continuing work monitoring the consumption of caffeine in Australia is also recommended by FSANZ to inform public health risk from caffeine.

While it cannot be guaranteed that the implementation of these recommendations will prevent another tragedy, FSANZ believe these recommendations, which traverse the wide and complex food regulatory system, are an appropriate response. They will support consumers to make safe decisions regarding caffeine consumption and will minimise access to high risk pure caffeine.

Recommendations

Recommendation one:

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

Recommendation two:

That FSANZ consider developing a maximum limit of caffeine in foods, based on the outcomes of the current review of Standard 2.9.4 – Formulated Supplementary Sports Foods. This work could be expedited, or the caffeine component could be separately progressed pending resources.

Recommendation three:

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

Recommendation four

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

Recommendation five

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

Introduction

This report was prepared in response to a request from the Minister for Aged Care and Senior Australians the Hon Richard Colbeck and the Minister for Health, the Hon Greg Hunt. The request follows the death of Mr Lachlan Foote in January 2018 which was attributed to acute caffeine toxicity associated with the consumption of a caffeine powder (refer Appendix A).

Specifically, the Ministers asked FSANZ to:

- consider and provide formal advice regarding the safety of caffeine powders and high caffeine content products, including current regulations and permissions for use of caffeine in the Australia New Zealand Food Standards Code (the Code)
- consider the need for appropriate warning labels and consumer safety information on caffeinated products
- engage with the Therapeutic Goods Administration regarding the relevant regulation for therapeutic goods that contain caffeine
- provide information about current caffeine permissions in the Code, and preliminary recommendations for strengthening regulations and consumer warnings by the end of August 2019.

This report summarises the outcomes of the review conducted by FSANZ as requested by Ministers. It outlines current regulations and permissions in the Code for the sale and use of caffeine in food, risks from caffeine consumption, makes recommendations for further action and outlines the next steps.

Approach

To ensure a broad range of views were captured FSANZ consulted with key stakeholders. These included Commonwealth agencies (the Department of Health, the Therapeutic Goods Administration (TGA) and the Department of Agriculture), food regulatory authorities from the States and Territories and New Zealand's Ministry for Primary Industries and New Zealand Medicines and Medical Devices Safety Authority.

A Working Group was established with representatives from each agency and weekly discussions were held to share information and identify issues and potential areas where regulatory and non-regulatory measures for caffeine could be strengthened.

FSANZ also liaised with international food regulation agencies regarding their approach to caffeine and reviewed existing analytical surveys and data to inform the recommendations within this report.

Noting timeframes for this review, FSANZ did not consult broadly with industry. In developing these preliminary recommendations, FSANZ has considered potential impacts to industry and, should these recommendations be accepted, will consult with industry on implementation of these.

The timeframes and consultative meetings were scheduled in accordance with Appendix B.

Findings

As mentioned above, this report was prepared in response to a request from the Minister for Aged Care and Senior Australians and the Minister for Health, the Hon Greg Hunt. Specifically, the Ministers asked FSANZ to:

- consider and provide formal advice regarding the safety of caffeine powders and high caffeine content products, including current regulations and permissions for use of caffeine in the Australia New Zealand Food Standards Code (the Code)
- consider the need for appropriate warning labels and consumer safety information on caffeinated products
- engage with the Therapeutic Goods Administration regarding the relevant regulation for therapeutic goods that contain caffeine
- provide information about current caffeine permissions in the Code, and preliminary recommendations for strengthening regulations and consumer warnings by the end of August 2019.

FSANZ's findings on each of the above are summarised below. Further evidence to support these findings is included in the background section and the appendices within this report.

The safety of pure and highly concentrated caffeine products

FSANZ's view is that pure or highly concentrated caffeine sold in a form that requires a very small safe dose to be measured from a potentially lethal amount poses an immediate and acute risk to consumers. Ingestion of small amounts can result in severe health effects, including death. Death has been reported after a single dose of 3 g caffeine, however a lethal dose is generally considered to be between 5 and 10 g (see the risk assessment page 22). The risk of serious health effects is compounded by the fact that these products can require fine scales (most kitchen scales measure in grams, not milligrams) to weigh an appropriate dose.

Similarly, this risk has been identified by the United States of America Food and Drug Administration which has deemed certain products consisting of only or primarily pure or highly concentrated caffeine to be 'adulterated' for the purposes of United States food law and, thereby, prohibited from sale. This occurred after these products were linked to at least two deaths in the United States.

FSANZ's view is that steps should be undertaken to prevent these products from being sold directly to consumers, whether as a food or otherwise.

The Department of Health, TGA, Department of Agriculture and jurisdictions shared FSANZ's view that pure or highly concentrated forms of caffeine can pose a risk at high dosage.

Risk posed by other caffeinated products sold as a food

FSANZ has not identified that other types of caffeinated products pose the same acute risk to consumers.

Caffeine as an ingredient in cola drinks and formulated caffeinated beverages (energy drinks) does not present a high risk given the maximum concentration of caffeine in these foods is already prescribed in the Code.

FSANZ is aware that a number of analogues or derivatives of caffeine exist naturally or can be chemically synthesised. Some of these substances have been added to sports foods together with caffeine although quantitative label declarations relate only to caffeine. The declared levels of caffeine in these products are much lower than in the same amount of a highly purified form and are therefore likely to have less severe health effects.

This is supported by an analytical program FSANZ commissioned on pre workout sports supplements in 2017 to determine the caffeine content of these foods. Data from 15 pre-workout sports supplement products indicated the highest average caffeine content for any one analysed product was about 4% caffeine or 387 mg/recommended pre-workout quantity. According to the European Food Safety Authority (EFSA) caffeine intakes up to 400 mg per day from all sources do not raise any safety concerns for the general population¹. Single doses of up to 200 mg consumed at one time do not raise safety concerns.

In July 2018, a roundtable on sports supplements was convened by the Australian Government Department of Health on behalf of the Food Regulation Standing Committee (FRSC). The roundtable consisted of consumer groups, the sports supplement industry and health professionals, the Australian Government and state and territory governments. The roundtable discussed current regulations for sports supplements and considered what can be done to enhance consumer safety. Following the roundtable Ministers requested FSANZ undertake a review of Standard 2.9.4 – Formulated Supplementary Sports Foods. The aim of this review is to update the Standard to reflect the changing sports supplement market.

Stage one of this work has commenced. This will inform the project scope and issues for the proposal, P1010 – Review of Formulated Supplementary Sports Foods. It will also examine the operation of Australian and New Zealand food/supplemented food/therapeutic good regulatory context for sports products including the Food Medicine Interface.

FSANZ will consider the potential health impacts of sports foods containing caffeine and caffeine analogues or derivatives, both those that occur naturally or that may be chemically synthesised, as a part of P1010.

FSANZ's view is that a maximum limit of caffeine should be considered and, if appropriate, applied broadly across foods. This maximum limit could be based on the outcomes of the review of Standard 2.9.4 – Formulated Supplementary Sports Foods.

The need for appropriate warning labels and consumer safety information on caffeinated products

As explained above, FSANZ 's view that pure or highly concentrated forms of caffeine sold in a form that requires a very small safe dose to be measured from a potentially lethal amount poses an immediate and acute risk to consumers and **is recommending that the retail sale of such products be banned**. If that action is not taken, then FSANZ's view is that, **at the very least, such products should be subject to requirements for warning labels and consumer safety information**. Work underway by the TGA to list certain caffeine preparations within Schedule 6 as a poison within the Poisons Standard will address this issue.

For other caffeinated products, the Code's current labelling and consumer safety information requirements in relation to caffeinated foods are the following:

¹ EFSA 2015 Scientific Opinion on the safety of caffeine. EFSA Journal 13(5):4102

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- Caffeine must be declared in the statement of ingredients if and when caffeine is added to a food for sale as an ingredient.
 - The following information must be provided on the labelling of formulated caffeinated beverages or energy drinks: a declaration of average quantity of caffeine per serving size and per 100 mL; and advisory statements that the product contains caffeine and that the product is not suitable for children, pregnant or lactating women and individuals sensitive to caffeine.

As part of the response to the Minister’s request to review caffeine, the Therapeutic Goods Administration has submitted an application to amend the Poisons Standard to include certain caffeine preparations in Schedule 6 of the Poisons Standard. Advice to FSANZ is that scheduling will impose additional packaging and labelling requirements for these preparations. For example, this listing will require containers of the listed preparation with a nominal capacity of 2 litres or less to comply with Australian Standard AS 2216-1997, entitled *Packaging for poisonous substances*. Containers with a nominal capacity of more than 2 litres must comply with subsection 1.4 (General Requirements) of Australian Standard AS 2216-1997 entitled *Packaging for poisonous substances* and be prominently labelled/embossed with the word “POISON”.

These additional packaging and labelling requirements will apply to caffeine when used as an additive (e.g., substances added to food to preserve flavour or enhance its taste, appearance, or other qualities) prior to their incorporation into food.

Action being taken by the Therapeutic Goods Administration

Pure-caffeine products cannot be lawfully supplied in Australia as a therapeutic good. The Therapeutic Goods (Permissible Ingredients) Determination²², which specifies ingredients and requirements for their use in listed medicines, provides that caffeine may not be used as the only active ingredient in a listed medicine (a therapeutic good). As a result, there are currently no (and cannot be) pure-caffeine listed medicines on the Australian Register of Therapeutic Goods (ARTG). Only therapeutic goods entered in the ARTG can be lawfully supplied in Australia.

The Therapeutic Goods Administration has amended the Therapeutic Goods (Permissible Ingredients) Determination to restrict the use and presence of highly concentrated caffeine in listed medicines, including as a component of herbal ingredients of listed medicines. This action will restrict the use of caffeine in listed medicines. It will have no impact on caffeine added to, sold in or as a food.

The Therapeutic Goods Administration has submitted an application to include caffeine within Schedule 4 and 6 of the Poisons Standard. As mentioned above, a consequence will be the imposition of additional packaging, storage and labelling requirements on the prescribed products. Advice to FSANZ is that exemptions in the Poisons Standard mean that any restrictions imposed as a result of that listing can only apply to the following foods:

- Food additives that contain or comprise the listed preparation but only prior to those food additives’ incorporation into food.
- Any food that is used as a means of administering the listed preparation for ‘therapeutic use’ (as defined by the *Therapeutic Goods Act 1989*).

²² <https://www.tga.gov.au/therapeutic-goods-determinations#pi>

All other foods would remain unaffected.

Australian food law – current permissions and restrictions

Australian State and Territory food laws prevent the sale of food that is unsafe or unsuitable. This prohibition applies regardless of any Code requirements. To the extent that the presence of pure or highly concentrated caffeine in a food renders that food unsafe or unsuitable, the sale of that food would be prohibited.

Australian food laws also require food for sale in Australia to comply with any relevant requirement set by the Code. In this regard –

- The Code expressly permits caffeine for use in cola type drinks (as a food additive) and in formulated caffeinated beverages. In both cases, this use is subject to compositional and labelling requirements.
- The Code does not contain a requirement that expressly prohibits the addition or use of caffeine in food per se. Nor does the Code contain a requirement that expressly prohibits the sale of pure or highly concentrated caffeine as a food.
- The Code's general prohibitions on the use of substances as food additives, processing aids and nutritive substances, unless expressly permitted, prevent the addition or use of caffeine in food in specific circumstances or for specific purposes. That is:
 - Caffeine cannot be used as a food additive in food (e.g. as a flavouring, colouring etc.) other than in cola type drinks.
 - Caffeine cannot be used as a processing aid in food or be added to food to achieve a nutritional purpose (noting that caffeine is unlikely to be used in this manner).

Laws relating to the access pathways for food to reach consumers were also considered.

Currently, access pathways for pure and highly concentrated caffeine products include domestic and international online retailers and is likely to include domestic shopfront retailers. According to the Department of Agriculture, it is common to have significantly large quantities of pure caffeine imported for manufacturing companies which are inspected; however, smaller quantities are also being imported through the mail without inspection. Further these goods imported via the mail are not normally subject to the FSANZ Code, assuming these products are not intended to on-sell, as the Code is not intended to regulate consumers.

The *Trans-Tasman Mutual Recognition Act 1997* (Cth) and *Trans-Tasman Mutual Recognition Arrangement* (TTMRA) between Australia and New Zealand must also be considered in this situation. Under the agreement, food which does not comply with the Code may still be imported into Australia from New Zealand provided it complies with New Zealand food law. These foods are also exempt from inspection under the Imported Food Control Act.

Recommendations

FSANZ has developed preliminary recommendations regarding the safety of high caffeine products based on consultation with key stakeholders and the findings from this review as outlined above. In particular recommendations reflect:

- It is apparent that the immediate and acute risk is the sale to consumers of pure or highly purified forms of caffeine that require a very small safe dose to be measured from a potentially lethal amount.
- Caffeine as an ingredient in cola beverages and formulated caffeinated beverages does not present a high risk given the concentration of caffeine in these foods is already prescribed in the Code.
- Current regulatory measures which include labelling requirements for foods containing caffeine.
- Work currently underway by TGA to restrict the sale of pure and highly concentrated caffeine medicines in certain circumstances.

Recommendation one

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

FSANZ's view is that there is an immediate and acute risk from the sale to consumers of pure or highly concentrated forms of caffeine that require a very small safe dose to be measured from a potentially lethal amount.

On this basis, action should be urgently undertaken to prevent pure or highly concentrated forms of caffeine from being supplied directly to consumers, whether as a food or otherwise.

Jurisdictions agree that pure or highly concentrated forms of caffeine supplied directly to consumers poses a high risk and were generally supportive of action being taken to address this risk.

To this end, and to complement action being taken by the TGA, FSANZ's preference is to initiate an urgent proposal to amend the Code to prohibit the retail sale of pure or highly concentrated forms of caffeine as a food.

An urgent proposal will enable a temporary measure to be put in place quickly to address the risk and protect consumers while broader issues with respect to the regulation of caffeine as a food by the Code or as a therapeutic good by the TGA Act can be worked through with the jurisdictions.

In the interim, the TGA will also progress the application for scheduling of caffeine preparations under the Poisons Standard and implement further restrictions on the use of caffeine in listed complementary medicines including restrictions on caffeine as a component of herbal ingredients in listed medicines.

Recommendation two

That FSANZ consider developing a maximum limit of caffeine in foods, based on the outcomes of the current review of Standard 2.9.4 – Formulated Supplementary Sports Foods.

A review of Standard 2.9.4 – Formulated Supplementary Sports Foods, is already underway as part of the action plan developed and agreed by the Australia and New Zealand Ministerial Forum on Food Regulation. The review includes a review of the levels of added sources of caffeine in supplementary sports foods. This review is anticipated to provide a mechanism for a separate proposal to examine additional restrictions on caffeine in food more generally: for example, a prohibition on the addition of caffeine to some or all foods (which would require permissions for certain foods); and/or creating a maximum caffeine limit in some or all food.

If a pressing need becomes apparent for this work, it could be expedited, or the caffeine component could be separately progressed, pending resources and prioritisation of this work compared to other priority work allocated to FSANZ by the Forum.

Recommendation three

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

An information campaign, developed at a national level in consultation with jurisdictions to raise awareness around dangers of pure caffeine powder, the safe levels of caffeine to consume in a sitting and in a day, and the dangers of ordering pure caffeine powder online.

This recommendation will have resource implications.

Recommendation four

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

Prior to any public campaign it is important that guidance materials or information is provided to food enforcement officers about high caffeine products on the market to assist them with enforcement decisions. This will be helpful for authorities to assist in preparation in dealing with complaints and enquiries generated as a result of the consumer information campaign.

To the extent that such guidance would be enforcement guidance, it should be developed and agreed by ISFR.

Input from the TGA and Ministry for Primary Industries in New Zealand may be required because the complexity of the issue lies in the intersection between requirements in food standards, therapeutic goods requirements and the sale of supplemented foods from or via New Zealand under the TTMRA.

Recommendation five

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

Continued monitoring of caffeine consumption across Australia would inform public health risk from caffeine.

Funding

Resourcing impacts for implementation of these recommendations is yet to be determined and is likely to extend beyond existing resourcing within FSANZ which is fully committed to meeting its statutory responsibilities. FSANZ will raise resourcing impacts with the Implementation Subcommittee for Food Regulations (ISFR), given the need for a coordinated approach across and by jurisdictions.

Background

Food-Medicine Interface

Medicines and other types of therapeutic goods are regulated by the Therapeutic Goods Administration in accordance with the *Therapeutic Goods Act 1989* (Cth).

Australian food laws regulate food. These laws define what is a food very broadly. A 'food' is defined to include 'any substance or thing of a kind used, or represented as being for use, for human consumption (whether it is live, raw, prepared or partly prepared)' and including anything used, or represented as being for use, as an ingredient or additive. This is regardless of whether or not the substance or thing is in a condition fit for human consumption.

Australian food laws do not apply to or regulate therapeutic goods. Australian food laws expressly state that a food does not include a therapeutic good within the meaning of the *Therapeutic Goods Act 1989* (Cth).

This means that, in Australia, caffeinated products may be regulated as either foods or medicines depending on the overall presentation - including advertising, claims, marketing material, and how the products are presented for supply to consumers, e.g. in capsules, tablets or 'shakes'. If a product containing purified caffeine makes therapeutic claims such as enhancing performance or increasing stamina, then it may be taken to be a therapeutic good as opposed to a food.

For some products, it is not immediately clear if they are a food or a medicine and therefore how they are regulated. Such products are described as being at the 'Food Medicine Interface'.

A Food Medicine Interface Guidance Tool has been developed to assist in determining whether a specific product is a food or a medicine/ therapeutic goods and therefore which set of regulations apply to that product. The Tool is administered by the Therapeutic Goods Administration.

The TGA has advised FSANZ that, in its view, pure or highly concentrated caffeinated products fall within the food and medicine interface. Products within this interface are assessed, and each assessment is considered individually on a product by product basis - as such depending on the individual circumstances of a caffeine containing product it may be determined to be either a food or therapeutic good. This outcome will therefore also determine which legislation applies. It is possible that a pure caffeine product assessed through the interface tool could be considered a food in which case the FSANZ Code should apply to that product. As such, the TGA agrees that a two-pronged approach to manage pure caffeine is preferable, with the FSANZ Code capturing those products that the interface indicate are a food and the TGA Act capturing those that are considered a therapeutic good.

Due to this complexity, FSANZ and the TGA agree that a two-pronged approach will best mitigate the potential risks - managing caffeine as both a food and a therapeutic good - via the Code for those products deemed to be food and via therapeutic goods legislation for those products deemed to be therapeutic goods. This approach is considered most pragmatic to manage acute toxicity risks, while further work is undertaken to determine if one legislative approach can be exclusively relied on.

As explained below, some action being taken by the Therapeutic Goods Administration in relation to medicines can and do have application to products sold as foods. Listing a

substance in a Schedule to the Poisons Standard can result in restrictions being imposed in relation to those substance use in foods to which that Standard applies.

Regulation of caffeine in, or as, therapeutic goods

The Therapeutic Goods Administration has provided FSANZ with the following advice in relation to the regulation of caffeine in or as a therapeutic good.

Caffeine does not have a specific entry in the Poisons Standard, therefore pure caffeine is currently unscheduled. However, products containing caffeine may be scheduled when used in combination with analgesics such as paracetamol in Schedule 2 and aspirin and salicylamide under Schedule 4.

Depending on scheduling, products other than these combinations containing small amounts of caffeine may be supplied off the shelf from pharmacies, health shops, and supermarkets provided they comply with the relevant requirements for either listed or registered medicines. For example, registered “Awakener” medicines such as “No-Doz” tablets and generics contain 100 mg caffeine per dose; while the dose per tablet when combined, e.g. with paracetamol in other registered medicines, is usually 65 mg (the usual dose of two tablets thus contains 130 mg caffeine). The maximum daily dose for over-the-counter medicines is 600mg.

Unlike registered medicines, there is no independent pre-market evaluation to assess the safety of listed medicine products. Instead, listed medicines may only contain certain pre-approved ingredients specified in the *Therapeutic Goods (Permissible Ingredients) Determination* (‘the Determination’) and comply with any requirements associated with their use. ‘Purified’ caffeine was permitted for use in listed medicines in 2012, at no more than 100 mg caffeine in the maximum daily dose (about the amount in a typical cup of coffee). The current Determination further states that caffeine may not be used as the only active ingredient. As a result, there are currently no (and cannot be) pure-caffeine listed medicines on the ARTG.

Caffeine may also be present in listed medicines as a component within herbal ingredients, such as *Camellia sinensis* (tea) and so caffeine can be present from multiple ingredients. Currently, there is no limit to the maximum caffeine content able to be derived in a product from herbal ingredients.

In 2018 the Therapeutic Goods Administration consulted on whether the maximum daily dose for caffeine as a component of herbal ingredients (and as an individual ingredient) was not to be more than 600 mg, with divided preparations for oral use to contain no more than 100 mg per dosage unit, to align with registered medicines. The Therapeutic Goods Administration delayed finalising proposed changes in response to feedback received from industry stakeholders and the potential for aligning with the European Food Safety Authority finding that habitual consumption of 400 mg caffeine/day in foods was not a concern in adults.

Action being taken by the Therapeutic Goods Administration in relation to caffeine

The Therapeutic Goods Administration is taking the following measures to address the safety concerns in relation to therapeutic goods (medicines) that contain of caffeine.

- a. TGA has submitted an application for reconsideration of the scheduling status of caffeine**

The main impact of this approach is that a scheduling classification would set expectations for the sale and supply of caffeine, irrespective of whether the product was represented as a food, medicine or industrial chemical.

The scheduling application will request listing certain preparations containing caffeine in Schedules 4 and 6.

These potential scheduling changes require two cycles of public consultation and committee meetings with notice periods subject to statutory timeframes. This, together with the need to provide sufficient notice to manufacturers to change and product packaging would mean that the earliest possible implementation of this option would likely be late 2020.

- The Poisons Standard is given legal effect by State and Territory poisons legislation. Listing will have the following effect under that legislation.
 - Preparations listed under Schedule 4. Retail sale by authorised practitioners, and by pharmacists on the prescription of such a practitioner. Wholesale sale may be made only by persons licensed or authorised to do so under the State and Territory poisons legislation.
 - Preparations listed under Schedule 6. No restriction on wholesale or retail sale. Packaging requirements, including type of packaging and warning and safety directions on the label. Storage requirements.

Exemptions in the Poisons Standard mean that these restrictions can only apply to the following foods:

- Food additives that contain or comprise the listed preparation but only prior to those food additives' incorporation into food.
- Any food that is used as a means of administering the listed preparation for 'therapeutic use' (as defined by the *Therapeutic Goods Act 1989*).

All other foods would remain unaffected.

b. TGA has implemented immediate amendments to the Permissible Ingredients Determination to control the availability of highly concentrated caffeine in listed medicines

i. All pure and highly concentrated caffeine products will become ineligible for listing

The Determination currently prevents 100% pure caffeine products for listing as complementary medicines including as a powder, the dosage form reported by the Coroner as the cause of death of Mr Foote. However, it does not prevent high concentrations of purified caffeine being used in listed medicines such as powders, liquids, or in products such as tablets that are primarily pure caffeine with some sugar and flavouring, which could still allow inadvertent overdose of caffeine. To address this risk, amendments to the Determination will be made by end August 2019 made to:

1. Restrict tablets/capsules from containing a caffeine concentration greater than 33%. This will not impact sponsors as there are currently no products on the ARTG more concentrated than this.

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2. Restrict powders and liquids from containing a caffeine concentration greater than 1%. At this concentration an entire 30g scoop of powder or 30 mL liquid would only deliver a 300 mg dose of caffeine.

ii. New restrictions on total caffeine content from all sources

The Determination was varied to align with the recommendations of EFSA to limit the total caffeine from all ingredient sources including as herbal components to a maximum daily dose to 400 mg.

Regulation of caffeine in, or as, a food

Australian State and Territory food laws prevent the sale of food that is unsafe or unsuitable. This prohibition applies regardless of any Code requirements. To the extent that caffeine's presence in a food renders that food unsafe or unsuitable, the sale of that food would be prohibited.

Australian food laws also require food for sale in Australia to comply with any relevant requirement set by the Code. The relevant Code provisions or requirements are summarised and explained in Appendix E and in Table 1.1 below.

In summary –

- The Code itself does not expressly prohibit addition or use of caffeine in food. Nor does the Code itself expressly prohibit the sale of pure or highly concentrated caffeine.
- To the extent that pure or highly concentrated caffeine is a novel food for the purposes of the Code, its retail sale as a food and its presence as an ingredient or component in a food for retail sale would be prohibited by the Code and State and Territory food laws. The status of pure or highly concentrated caffeine as a novel food remains arguable and untested by food regulators and the courts.
- The Code imposes prohibitions on the use of substances as food additives, processing aids and nutritive substances, unless expressly permitted. These prohibitions only apply to substances that fall with the Code's definition of what constitutes a food additive, a processing aid or a nutritive substance for the purposes of these prohibitions.

These prohibitions prevent the addition or use of caffeine in food in specific circumstances or for specific purposes. That is:

- Caffeine that meets the test of what constitutes "a food additive" (as defined) cannot be used in food other than in cola type drinks.
- Nor can caffeine be used in food as 'a processing aid' (as defined) or as nutritive purpose (as defined) (noting that caffeine is unlikely to be used in this manner).
- There is a lack of clarity in situations where caffeine's use in or addition to food does not fall with the Code's definition of what constitutes 'a food additive', 'a processing aid' or 'a nutritive substance'. There is no express requirement in the Code that prohibits caffeine's use in or addition to food for such other purposes. Two exceptions are the Code's restrictions on novel food and its reference to formulated caffeinated beverages having the purpose of 'enhancing mental performance'.

To the extent that caffeine is not a novel food (see above), the absence of any express

requirement permits an argument that, as a matter of statutory interpretation, the Code itself does not prohibit the addition of caffeine to food if that addition is for another purpose. An example may be the addition or use of caffeine in food as stimulant' such as in sports supplements foods. FSANZ's view is that addition or use as a stimulant would not meet the test for use as 'a food additive', 'a processing aid' or as 'a nutritive substance'. As such, that addition or use is not captured by the above-mentioned prohibitions. This argument remains untested by food regulators and the courts.

- The Code expressly permits caffeine for use in cola type drinks (if used as a food additive – as defined) and in formulated caffeinated beverages. In both cases, this use is subject to compositional and labelling requirements.

Table 1.1.

Product	Current risk management/amount in food
Any food containing caffeine as an ingredient	<ul style="list-style-type: none"> > A Code requirement to declare added caffeine in the ingredient list. > A requirement that the food product be safe and suitable (as required by the Food Acts).
Formulated caffeinated beverages (energy drinks)	<ul style="list-style-type: none"> > The Code restricts the amount of caffeine (maximum of 320 mg per litre). > Mandatory labelling advisory statements that the food contains caffeine and is not recommended for children (no defined age), pregnant or lactating women and individuals sensitive to caffeine. > Labels must also declare the maximum number of serves per day (based on content of certain nutrients rather than caffeine). > A requirement that the food product be safe and suitable (as required by the Food Acts).
Formulated supplementary sports foods (e.g. pre-workout supplements, protein powders)	<ul style="list-style-type: none"> > May be regulated as either a food or a therapeutic good depending on the individual products' presentation and whether it meets the definition of a food in the FSANZ Act, or the definition of a therapeutic good in the <i>Therapeutic Goods Act 1989</i>. > No express permissions for caffeine in formulated supplementary sports foods in the Code. > Standard 2.9.4 currently under review – caffeine and labelling to be considered as part of this. > A requirement that the food product be safe and suitable (as required by the Food Acts).
Cola type drinks	<ul style="list-style-type: none"> > The Code restricts the amount of caffeine (total caffeine must not exceed 145 mg/kg). > Labelling advisory statement 'contains caffeine'. > A requirement that the food product be safe and suitable (as required by the Food Acts).

Food containing guarana or extracts of guarana	<ul style="list-style-type: none"> > Labelling advisory statement ‘contains caffeine’ > A requirement that the food product be safe and suitable (as required by the Food Acts).
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Maximum limits for caffeine in the Code

It is unclear in the Code whether the addition of caffeine to foods requires an explicit permission. An example of foods that contain added caffeine that do not have such a permission is formulated supplementary sports foods. As these can be consumed at levels which present an acute health risk it is recommended that a permission and a maximum level is considered. FSANZ will therefore undertake a review of the Code to determine the need for additional express restrictions on added caffeine in food: for example, an express prohibition on the addition of caffeine to some or all foods (which would require permissions for certain foods); and/or creating a maximum caffeine limit in some or all food products.

Statutory framework and requirements for Code amendments

As explained above, there is a lack of clarity in the Code in relation to the regulation of caffeine as a food. For the following reasons, a considered approach to rectifying this issue must be taken.

FSANZ’s ability to act is determined by the FSANZ Act. Standards development and the amendment of the Code is governed by and must occur in accordance with that Act. That Act requires all proposed amendments must undergo an evidence based assessment against statutory criteria and be the subject of public consultation. The Act also provide certain stakeholders with the right to seek review of FSANZ’s decisions.

When considering changes to the Code, FSANZ must consider a number of important criteria to ensure a standard is the best measure to manage an identified risk. The most important criteria is that the scientific weight-of-evidence points to a potential source of harm that requires some level of regulatory intervention to protect public health and safety.

In addition to public health and safety, there are other considerations that must be taken into account when determining the need to establish a standard:

- **Costs/benefits** – FSANZ assesses the costs/benefits to consumers, jurisdictional enforcement agencies implementing a standard and food businesses complying with a standard. In the case of establishing a maximum level for caffeine in food, it is important that only those products posing a demonstrated public health and safety concern are captured and doesn’t result in unintended consequences for other foods.
- **Existing risk management measures** – Even if a risk to public health and safety is identified by FSANZ through a risk assessment process, there may already be measures in place to manage the identified risk. If current risk management measures are adequate then there is no rational basis to impose additional regulation. For example, in the case of formulated caffeinated beverages, it is important to note current labelling standards to limit excessive exposure and to protect vulnerable populations, such as children and pregnant women.
- **Practicality of risk management options** – Intuitively, a standard would only be set where it is the best option available to manage a risk. Part of this consideration includes the availability of a suitable validated analytical method for compliance testing. FSANZ also has scope within its legislation to investigate non-regulatory options, which

in practice, may be a better fit to achieve public health and safety. Non-regulatory options include tangibles like consumer or industry advice (e.g. advertising, infographics or guidance material), recommended serving sizes etc.

- Public consultation – FSANZ’s processes are open and transparent, with a legislative requirement (in most cases) to undertake at a least one round of public consultation.
- Urgency of a standard – In addition to the two main pathways that FSANZ has to establish standards – applications and proposals – there is also the option for FSANZ to declare an application or a proposal as urgent. However, it is important to note that this urgent pathway still has at its centre the criterion of the protection of public health and safety. In other words, there needs to be a demonstrable or highly anticipated risk to public health and safety before FSANZ could declare an urgent application or proposal.

Imported food

Foods imported into Australia are subject to requirements including the *Imported Food Control Act 1992* (IFC Act) for compliance with Australian food standards and the requirements of public health and safety. Under the IFC Act, importers are legally responsible for complying with the standards that apply to their products to ensure they are safe and suitable for their intended use.

Under section 8 of the *Imported Food Control Act 1992*, it is an offence to import food into Australia if the importer knows, or ought reasonably to have known, that it poses a risk to human health. The offence carries a penalty of imprisonment for 10 years.

Section 16 of the IFC Act provides for the department to administer the Imported Food Inspection Scheme (IFIS). The *Imported Food Control Regulations 1993* sets out how the IFIS operates including the rates that foods are referred for inspection. For the operation of the IFIS, foods are either classified as risk food and are scheduled in the *Imported Food Control Order 2001* (the Order) or are surveillance food.

Orders to classify food are made by the Minister based on risk advice from FSANZ. Food may be classified as risk food if FSANZ advises that the food has the potential to pose a medium to high risk to public health. The requirement for consultation with FSANZ on the risk classification of a food is outlined in Section 17 of the IFC Act.

Management of caffeine products under the IFIS

The Department of Agriculture considers four standards in relation to food likely to contain caffeine:

- Standard 2.6.2 Non-alcoholic beverages and brewed soft drinks
- Standard 2.6.4 Formulated caffeinated beverages
- Standard 2.9.3 Formulated meal replacements and formulated supplementary foods
- Standard 2.9.4 Formulated supplementary sports foods.

Foods under these standards are surveillance foods and are inspected for compliance via product presentation and labelling checks against relevant standards in Chapter 1 and Chapter 2 of the Code, as specified in instructional material.

Currently, products imported through the mail system are only directed for inspection if they are greater than 10 kgs. The Department of Agriculture are undergoing the necessary

changes to reduce this limit to 1 kg. This change is anticipated to improve the detection rate at the border of high risk commodities weighing between 1 and 10 kgs.

However, due to the vast quantity of mail arriving into Australia daily, it is not practical for every arrival to be inspected. Food arriving via the mail pathway is out of scope of the IFIS and as such it is not referred to the Department for assessment and inspection.

Further detail is provided at Appendix E.

Food imported into Australia from New Zealand

The *Trans-Tasman Mutual Recognition Act 1997* (Cth) and Trans-Tasman Mutual Recognition Arrangement (TTMRA) between Australia and New Zealand provides that food which does not comply with the Code (as applied by the Food Acts) may be imported into Australia from New Zealand and sold in Australia provided it complies with the New Zealand food law. With the exception of a few risk foods specified in the Order, it is also exempt from inspection under the IFC Act.

New Zealand food law includes the *Dietary Supplements Regulations 1985* and the *New Zealand Supplemented Food Standard 2016* which regulates 'supplemented food'. There is no restriction on the level of caffeine that may be added to a supplemented food under the New Zealand Standard. However, if a supplemented food contains a level of caffeine greater than is required to achieve a technological function under conditions of Good Manufacturing Practice, the New Zealand Standard requires that certain advisory statements be present on the label and the average quantities of caffeine per serve and per 100 mL (or 100g) must be declared in the nutrition information panel.

The TTRMA's operation and impact remain matters for Government and are outside the scope of this report.

Policy guidance for food regulation of caffeine

The Forum (then convening as the Australia and New Zealand Food Regulation Ministerial Council) agreed to a new policy guideline on the regulatory management of caffeine in the food supply in June 2014³. The policy guideline includes the following specific policy principles:

The regulatory management of caffeine in the food supply should:

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

It also includes the following additional policy guidance:

³ The policy guidance is available at <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Caffeine-to-Foods>.

FSANZ is encouraged to work with research agencies to monitor caffeine consumption across the population, including consumption by vulnerable population groups.

Regulatory management of caffeine in the food supply may include regulatory and non-regulatory risk management approaches.

Risk assessment – caffeine in food

There is no established health-based guidance value, such as an Acceptable Daily Intake, for caffeine.

A FSANZ Expert Working Group analysed the available literature in 2000 and concluded that there was evidence of increased anxiety levels in children at doses of about 3 mg of caffeine per kilogram of bodyweight per day⁴. The anxiety level for children aged 5-12 years equates to a caffeine dose of 95 mg per day (approximately two cans of cola) and about 210 mg per day (approximately three cups of instant coffee) for adults.

The European Food Safety Authority (EFSA)⁵ and the United States Food and Drug Administration⁶ have concluded that a total caffeine intake of 400 mg/day (5.7 mg/kg bodyweight/day) is safe for most adults, although EFSA recommends that pregnant women should not consume more than 200 mg/day, and notes that a single dose of approximately 1.4 mg/kg bodyweight taken shortly before bedtime may disrupt sleep patterns.

Consumption of caffeine in excess of recommended safe levels increases the risk of tremors, high blood pressure, dizziness, confusion, panic, heartburn, nausea, vomiting, cardiac arrhythmia and racing heartbeat (tachycardia)⁷.

Death has been reported after a single dose of 3 g caffeine, however a lethal dose is generally considered to be between 5 and 10 g⁸.

FSANZ's view is that the immediate and acute risk is that posed by the sale of pure or highly purified forms of caffeine to consumers. Ingestion of small amounts of these substances can result in severe health effects, including death. The risk of serious health effects is compounded by the fact that these products require fine scales (most kitchen scales measure in grams, not milligrams) to weigh an appropriate dose. Caffeine as an ingredient in foods such as formulated caffeinated beverages and sports foods does not present such a high risk given the concentration of caffeine in these foods is likely to be less.

⁴ <http://www.foodstandards.gov.au/publications/Documents/safety%20aspects%20of%20dietary%20caffeine.pdf>

⁵ EFSA 2015 Scientific Opinion on the safety of caffeine. EFSA Journal 13(5):4102

⁶ [fda.gov/consumers/consumer-updates/spill-beans-how-much-caffeine-too-much](http://www.fda.gov/consumers/consumer-updates/spill-beans-how-much-caffeine-too-much)

⁷ Cappelletti S, Piacentino D, Sani G, Aromatario M. (2015). Caffeine: Cognitive and Physical Performance Enhancer or Psychoactive Drug? Curr Neuropharmacol 13(1): 71-88

⁸ Wilson C. (2018). The clinical toxicology of caffeine: A review and case study. Toxicol Rep 5:1140-1152.

Wikoff et al. (2017). Systematic review of the potential adverse effects of caffeine consumption in healthy adults, pregnant women, adolescents and children. Food and Chemical Toxicology 109(1): 585-684.

Analogue or derivatives of caffeine

FSANZ is aware that a number of analogues or derivatives of caffeine exist naturally or can be chemically synthesised⁹. Some of these substances have been added to sports foods, together with caffeine although quantitative label declarations relate only to caffeine. The declared levels of caffeine in these products are much lower than in the same amount of a highly purified form and the health effects as a result of caffeine concentrations are therefore likely to be less severe.

Added caffeine in pre-workout sports supplements

FSANZ commissioned an analytical program on pre-workout sports supplements in 2017. Data from 15 pre-workout sports supplement products indicated the highest maximum average caffeine concentration in one product was 4253 mg/100 g (range in this product 2602 – 5879 mg/100g). These supplements contain scoops inside the product and the label recommends the number of scoops to consume prior to a workout. The data showed that, when expressed per pre-workout, and assuming only one workout per day, the highest average caffeine content for any one analysed product was 387 mg/recommended pre-workout quantity.

Actions underway

A high priority action is the reporting of non-compliant imported products to the Department of Agriculture. The Department of Agriculture has requested FSANZ undertake a risk assessment of imported sports supplements. It is expected that the risk assessment will support an increased inspection rate of imported products at the border which will assist in preventing non-compliant products entering the Australian market. This work is being undertaken as part of the review of Standard 2.9.4.

The Department of Agriculture has also initiated an application for three new tariff codes for imported formulated supplementary sports foods, formulated caffeinated beverages, formulated supplementary foods and meal replacements. This will enable improved targeting and compliance inspection of these products prior to sale. This is expected to be scheduled for implementation by July 2020.

Currently the Inspection Scheme applies to food imports greater than 10 kg. Food imports less than 10 kg are considered as private consumption and are exempt from the Act. Amendments to the Regulations (after 1 October 2019) will see this limit reduced from 10 kg to 1 kg.

⁹ Bello ML, Walker AJ, McFadden BA, Sanders DJ, Arent SM. (2019). The effects of TeaCrine® and caffeine on endurance and cognitive performance during a simulated match in high-level soccer players. *J Int Soc Sports Nutr.* 16(1):20.

Daly JW, Padgett WL, Shamim MT. (1986). Analogues of caffeine and theophylline: effect of structural alterations on affinity at adenosine receptors. *J Med Chem* 29(7):1305-8.

Murbach TS, Glavits R, Endres JR, Clewell AE, Hirka G, Vertesi A, Beres E, Pasics Szakonyine I. (2019) A toxicological assessment of methylxanthines. *The Toxicologist: Late-Breaking Supplement, Supplement to Toxicological Sciences*, 168 (1), Abstract # 3541

Müller CE, Jacobson KA. (2011) Xanthines as adenosine receptor antagonists. *Handb Exp Pharmacol.* 200:151-99.

Monitoring of caffeine consumption

FSANZ included caffeine in the 2011-13 Australian Food, Supplement and Nutrient (AUSNUT) food composition file, which was used by the Australian Bureau of Statistics (ABS) to estimate caffeine intakes in the 2011-13 Australian Health Survey (AHS)¹⁰ for the population aged 2 years and above.

Conclusions were:

- Respondents over 30 years of age consumed more caffeine compared to younger age groups, with mean usual intakes over 160 mg/day (over 4 cups black tea or 1.5 shots espresso coffee per day).
- Children up to 18 years get most of their caffeine from water based flavoured drinks (cola and energy drinks), followed by coffee and tea and some from chocolate/cocoa containing foods. Adults get most of their caffeine from coffee and tea.
- Some respondents also reported having caffeine intakes from dietary supplements (such as multivitamin, stress, detox, herbal, guarana containing supplements)¹¹.

International approaches – caffeine in or as food

The following provides an overview of the regulation of caffeine for sale to consumers in the United States of America (USA), Canada and the European Union. There is no consistent approach to regulation across the countries as outlined in the table below.

Further detail is provided in Appendix F.

	Pure and highly concentrated caffeine	Foods with added caffeine	Foods with natural caffeine
USA	Some products consisting of only or primarily pure or highly concentrated caffeine considered to be adulterated and hence sale prohibited.	Caffeine may be used as an ingredient in foods provided it has been determined as Generally Recognised as Safe. No labelling requirements specifically for caffeine.	No compositional limits or labelling requirements specifically for caffeine.
Canada	Permitted for retail sale. Regulated as licensed natural health products. Labelling requirements include recommended dose and duration of use and risk information (generic requirement).	Addition of caffeine regulated as a food additive. Permitted in some beverages up to specified limits. Specific labelling requirements for caffeinated energy drinks.	No compositional limits or regulatory requirement to identify the presence of or amount of caffeine for natural sources.
European Union (EU)	European Commission directive does not include compositional limits but EU	Use of caffeine as a flavouring substance in food is subject to restrictions of use in certain	Specific warnings required for some foods, excluding

¹⁰ Australian Bureau of Statistics (2014), Australian Health Survey: <https://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/4364.0.55.0072011-12?OpenDocument>

¹¹ ABS (2014), National Nutrition and Physical Activity Survey, 2011–12, Basic CURF. Australian Government, Canberra. <http://www.abs.gov.au/AUSSTATS/abs@.nsf/Latestproducts/4324.0.55.002Main%20Features652011-12?opendocument&tabname=Summary&prodno=4324.0.55.002&issue=2011-12&num=&view>

	<p>member states may develop these. Labelling requirements for recommended daily consumption.</p>	<p>food categories. No compositional rules if added for a nutritional or physiological effect. Specific warnings required for caffeine. The actual caffeine content must also be on the label.</p>	<p>beverages based on coffee, tea or coffee or tea extract where the name of the food includes the term 'coffee' or 'tea'.</p>
<p>Australia and New Zealand</p>	<p>Food Acts prevent the sale of unsafe or unsuitable food. Food Standards Code does not expressly prohibit the sale of pure or highly concentrated caffeine.</p>	<p>Food Acts prevent the sale of unsafe or unsuitable food. The Code does not expressly prohibit addition or use of caffeine. Caffeine is in effect prohibited for certain categories of foods. Caffeine expressly permitted up to maximum levels in cola type drinks and formulated caffeinated beverages (FCBs). 'Contains caffeine' required for these foods. Advisory statements and quantitative declaration of caffeine for FCBs.</p>	<p>Food Acts prevent the sale of unsafe or unsuitable food. No compositional limits in the Code. 'Contains caffeine' labelling statement required for foods containing guarana.</p>

Appendix A: Request from the Hon Richard Colbeck, Minister for Aged Care and Senior Australians, Minister for Youth and Sport



SENATOR THE HON RICHARD COLBECK
Minister for Aged Care and Senior Australians
Minister for Youth and Sport

Mr Mark Booth
Chief Executive Officer
Food Standards Australia New Zealand (FSANZ)
Po Box 5423
KINGSTON ACT 2604

10 JUL 2019

cc- Ms Robyn Kruk AO

Dear Mr Booth

On behalf of Minister Hunt and myself, I am writing in relation to the tragic death of a young man in New South Wales, Mr Lachlan Foote. Mr Foote's death was attributed to acute caffeine toxicity associated with the consumption of a caffeine powder.

Following this incident, I write to request FSANZ consider and provide formal advice regarding the safety of caffeine powders and high caffeine content products, including current regulations and permissions for use of caffeine in the Australia New Zealand Food Standards Code (the Code). I also request consideration be given to the need for appropriate warning labels and consumer safety information on caffeinated products. I also request that as part of your review that you engage with the Therapeutic Goods Administration regarding the relevant regulation for therapeutic goods that contain caffeine.

I would appreciate you providing Minister Hunt and myself with information about current caffeine permissions in the Code, and preliminary recommendations for strengthening regulations and consumer warnings by the end of August 2019.

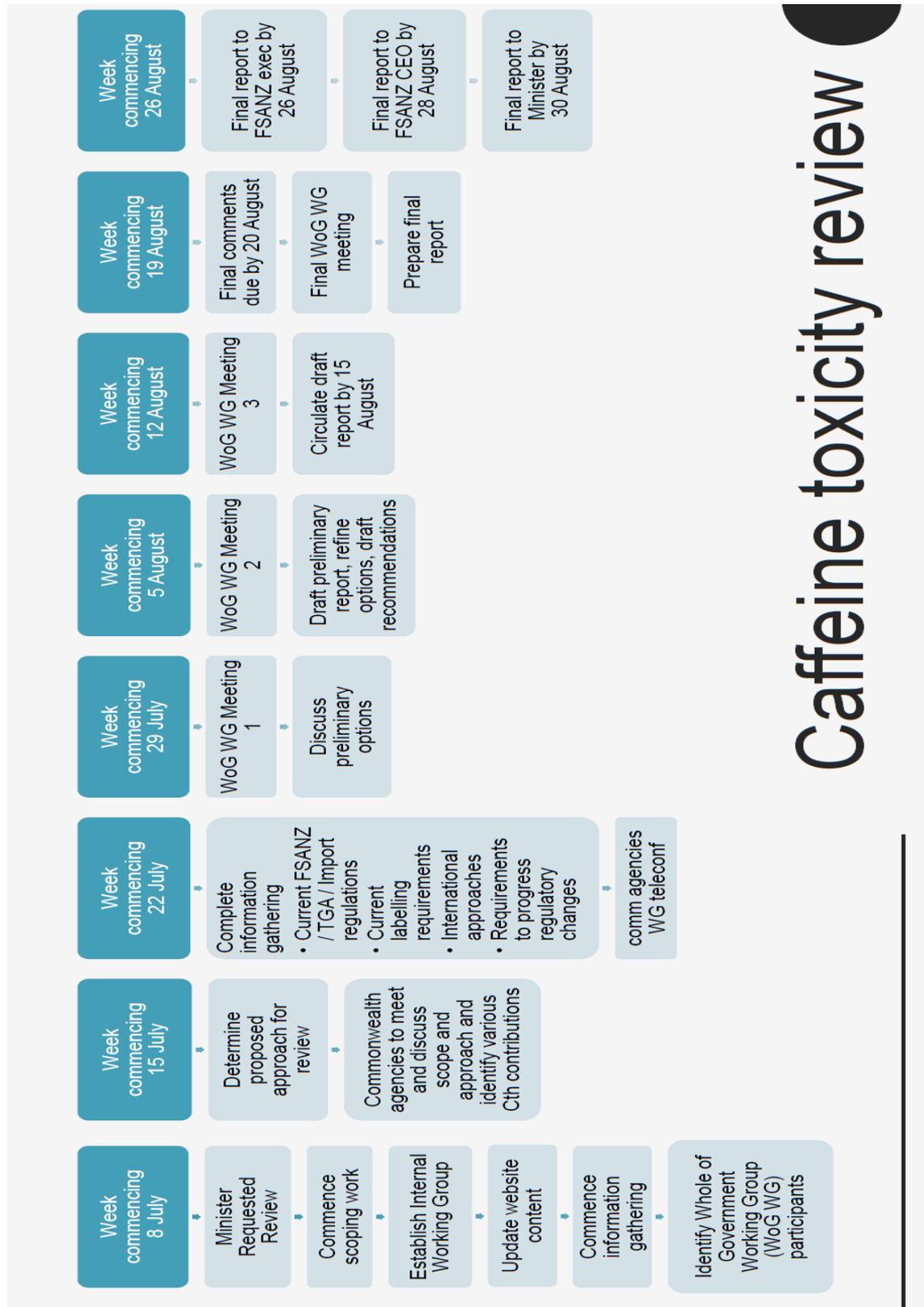
I appreciate your support in protecting Australians from dangers such as these.

Yours sincerely

A handwritten signature in blue ink that reads "Richard Colbeck".

Richard Colbeck

Appendix B: Summary of consultations



Appendix C: History of caffeine regulation in Australia

The below table represents a timeline of major reviews and changes to the Code in relation to caffeine.

July 2019	Senator the Hon Richard Colbeck together with Minister Hunt requested FSANZ provide information about current caffeine permissions in the Code and preliminary recommendations for strengthening regulations and consumer warnings for caffeine powders and high caffeine content products by the end of August 2019.
July 2018	On 24 July 2018, a roundtable on sports supplements was convened by the Australian Government Department of Health on behalf of the Food Regulation Standing Committee (FRSC). The roundtable consisted of consumer groups, the sports supplement industry, health professionals, the Australian Government and state and territory governments.
June 2014	The Australia and New Zealand Food Regulation Ministerial Council agreed to a new policy guideline on the regulatory management of caffeine in the food supply.
September 2013	FRSC released a Consultation Paper for public consultation on a Food Regulation Policy Options Paper for formulating policy guidelines on the regulation of caffeine in the Australian and New Zealand food supplies.
May 2011	On 6 May 2011 the Ministerial Council agreed to a comprehensive review of the 2003 policy guideline, noting the increased number of energy drinks on the market containing caffeine and other exotic ingredients.
April 2003	On 4 April 2003 the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) agreed to a policy guideline on the addition of caffeine to foods. The Ministerial Council agreed, until further evidence became available, to maintain the status quo for caffeine regulation by: <ul style="list-style-type: none">• Maintaining the current additive permissions for caffeine; and• Restricting the use of new products containing non-traditional caffeine rich ingredients (including guarana) to boost the caffeine content in other food, beyond the current provisions for caffeine.
2001	Standard 2.6.4 – Formulated Caffeinated Beverages was gazetted.
Pre-2001	Only permission in the Code to add caffeine to food was in the context of caffeine as a food additive (flavouring) in kola-type beverages

Appendix D: Caffeine prohibitions and permissions in the Code

The Food Acts – compliance with Code requirements

The Code has no effect of itself. It relies on the Food Acts for its legal effect. The Food Acts make it an offence to sell or offer for sale any food that does not comply with a requirement of the Code.

The Code

Scope

Food

The Code only applies to food as defined by the Food Acts and the *Food Standards Australia New Zealand Act 1991* (Cth). Section 5(2) of that Act provides, for example, that food does not include a therapeutic good with the meaning of the *Therapeutic Goods Act 1989* (Cth). The latter Act provides that a food (e.g. a product covered by a Standard in the Code or which is traditionally used or consumed as a food) may be declared to be a therapeutic good for its purposes.

Relevant Code sections: 1.1.2—2(2) and the definition of food in section 1.1.2—2(3)

Not all food

The Code also only applies to food that is sold or that is processed or handled for sale; or imported into Australia or New Zealand.

Relevant Code sections: 1.1.1—3

Food imported into Australia from New Zealand

The *Trans-Tasman Mutual Recognition Act 1997* (Cth) and Trans-Tasman Mutual Recognition Arrangement between Australia and New Zealand provides that food which does not comply with the Code (as applied by the Food Acts) may be imported into Australia from New Zealand and sold in Australia provided it complies with the New Zealand food law.

New Zealand food law includes the *New Zealand Supplemented Food Standard* which regulates ‘supplemented food’: that is, products represented as a food that has a substance or substances added to it or that has been modified in some way to perform a physiological role beyond the provision of a simple nutritive requirement³. There is no restriction on the level of caffeine that may be added to a supplemented food under the New Zealand Standard. However, if a supplemented food contains a level of caffeine greater than is required to achieve a technological function under conditions of Good Manufacturing Practice, the New Zealand Standard requires that certain advisory statements be present on the label and the average quantities of caffeine per serve and per 100ml (or 100g) must be declared in the nutrition information panel.

Naturally occurring caffeine in food

The prohibitions in the Code generally do not apply to substances that are in a food for sale or in an ingredient in a food for sale by natural occurrence.

- That is, the prohibitions do not apply to caffeine that is naturally occurring or present in coffee and cocoa beans, tea leaves, guarana berries and the kola nut when the latter foods are a food for sale or an ingredient in a food for sale.

Relevant Code sections: 1.1.1—10(7)

Foods containing caffeine

The Code provides that a food for sale may consist of, or have as an ingredient, any food. That is –

- Foods that contain naturally occurring caffeine may be an ingredient in a food for sale (i.e., coffee and cocoa beans, tea leaves, guarana berries, kola nuts)
- Foods permitted by the Code to contain added caffeine may be an ingredient in a food for sale – subject to any compositional and other requirement imposed by the Code. See for example, the prohibition referred to below on a food for sale being a mixture of a non-alcoholic beverage and a formulated caffeinated beverage.

Relevant Code sections: 1.1.1—10(2)

The Code requires foods for retail sale that contain guarana or extracts of guarana (i.e. a food with naturally occurring caffeine) to be labelled with an advisory statement that the food contains caffeine.

Relevant Code sections: 1.1.1—10(8) and (9), 1.2.1—6(1), 1.2.1—8(1)(d), 1.2.3—2(1), 2.9.5—10(2)(a), Item 6 of the Table to section S9—2.

Caffeine extracts

The following discussion relates to pure or highly concentrated caffeine extracts (powders or liquids). It does not relate to foods that contain caffeine by natural occurrence or the addition or use of such foods to or in other foods

Prohibited as a novel food?

The Code prohibits a food for retail sale from being, or having as an ingredient, a novel food unless expressly permitted by the Code.

The Code defines a novel food to mean ‘a non-traditional food that requires an assessment of the public health and safety considerations having regard to’ prescribed criteria, including ‘the potential for adverse effects in humans’.

A non-traditional food is defined to mean:

- (a) a food that does not have a history of human consumption in Australia or New Zealand; or
- (b) a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or

-
- (c) any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand

It could be argued, for example, that pure or highly concentrated caffeine is a substance that:

- is derived from another food or foods;
- does not itself have a history of human consumption in Australia or New Zealand; and
- requires an assessment of the public health and safety considerations having regard to the criteria prescribed by the Code, particularly 'the potential for adverse effects in humans'.

However, such a position remains arguable and the shortcomings of the novel food standard, particularly in an enforcement context, are well documented.

The novel food Standard is being reviewed in Proposal P1024.

Relevant Code sections: 1.1.1—10(5)(b), 1.1.1—10(5)(f), 1.1.2—8.

Caffeine cannot be used as a food additive – all foods

With one exception, the Code does not permit caffeine to be used as a food additive.

Section 1.1.1—10(6)(a) prohibits a food for sale having as an ingredient or a component a substance that was 'used as a food additive' unless expressly permitted by the Code.

The Code does not list permissions for caffeine to be used as a food additive

The one exception is use as a food additive in Cola type drinks. This use is subject to:

- a compositional requirement; total caffeine content must not exceed 145 mg/kg in the drink as consumed.
- labelling requirements.

Caffeine must be listed in the statement of ingredients as caffeine and the product label must bear an advisory statement to the effect that the product contains caffeine.

It is important to understand that the Code provides that a substance is 'used as a food additive' in relation to food if:

- it is added to food to perform one or more of the functions listed in Schedule 14 of the Code; and
- it is a substance identified in section 1.1.2—11 (2)

This means that, if a substance is added to a food to perform a function other than one listed in Schedule 14 or if it is not listed in section 1.1.2—11 (2), it is not a substance used as a food additive for the purposes of the Code. That is, that substance is not subject to or restricted by the prohibition imposed by section 1.1.1—10(6)(a).

Relevant Code sections: 1.1.1—10(6)(a), 1.1.2—11. 1.3.1—3, Schedule 15, Item 14.1.3.0.2 of the Table to section S15-5

1.1.1—10(3)

1.1.1—10(9), 1.2.4—7(6)

1.1.1—10(8), 1.2.1—8(1)(e), 1.2.4—3

The product label on a food that contains a cola beverage that also contains added caffeine as an ingredient must also bear an advisory statement to the effect that the product contains caffeine.

Relevant Code sections: 1.1.1—10(9), 1.2.1—6(1), 1.2.1—8(1)(d), 1.2.3—2(1), Item 8 of the Table to section S9—2.

Caffeine cannot be used as a processing aid – all foods.

The Code does not permit caffeine to be used as a processing aid. That is, be added to food to perform a technological purpose during the processing of food.

Relevant Code sections: 1.1.1—10(6)(c), 1.1.2—13, Standard 1.3.3, Schedule 18

Caffeine cannot be used as a nutritive substance – all foods

The Code does not permit caffeine to be used as a nutritive substance. That is, be added to food to achieve a nutritional purpose.

Relevant Code sections: 1.1.1—10(6)(b), 1.1.2—12. Standard 1.3.2 (Vitamins and minerals), Standard 2.9.1 (Infant formula products), Standard 2.9.2 (Food for infants), Standard 2.9.3 (Formulated meal replacements), Standard 2.9.4 (Formulated supplementary sports foods) and Standard 2.9.5 (Food for special medical purposes), Schedules 17, 28 and 29.

Formulated caffeinated beverages (energy drinks)

The Code permits the use of caffeine in formulated caffeinated beverages or energy drinks (e.g., such as Red Bull) subject to conditions.

The Code defines a *formulated caffeinated beverage* to mean ‘a flavoured, non-alcoholic beverage, or a flavoured, non-alcoholic beverage to which other substances (for example, carbohydrates, amino acids and vitamins) have been added, that:

- (a) contains caffeine; and
- (b) has the purpose of enhancing mental performance’.

The use of caffeine in formulated caffeinated beverages is subject to:

- a compositional requirement; the drink must contain no less than 145 mg/L and no more than 320 mg/L of caffeine in total, from any source.
- labelling requirements, including: a declaration of average quantity of caffeine per serving size and per 100mL; and advisory statements that the product contains caffeine and that the product is not suitable for children, pregnant or lactating women and individuals sensitive to caffeine.

The Code also prohibits a food for sale being a mixture of a non-alcoholic beverage and a formulated caffeinated beverage.

Relevant Code sections: 1.1.1—10(2) and (3), 1.1.2—2, 1.1.2—6, Standard 2.6.4, Schedule 28

1.1.1—10(8) and (9), 1.2.1—6(1), 1.2.1—8(1)(d),

Formulated meal replacements and formulated supplementary foods.

Standard 2.9.3 sets compositional and labelling requirements for foods that are formulated meal replacements or formulated supplementary foods. The compositional requirements relate only to protein, kilojoules carbohydrates, vitamins and minerals.

None of the requirements provide an express permission for the addition or use of caffeine in these foods (e.g., use as a nutritive substance).

Formulated supplementary sports foods.

Standard 2.9.4 sets compositional and labelling requirements for foods that are formulated supplementary sports foods.

None of the Standard's sections or requirements provide an express permission for the addition or use of caffeine in these foods (e.g., including as a nutritive substance, food additive, processing aid).

FSANZ has commenced a review of Standard 2.9.4 in June 2019 (Proposal P1010).

Foods for special medical purposes

Standard 2.9.5 sets compositional, labelling and other requirements for foods that are a food for special medical purpose.

Unlike Standard 2.9.3 and 2.9.4, Standard 2.9.5 expressly provides that the restrictions imposed by certain other Standards, including on the use of nutritive substances and on novel foods, do not apply to a food for special medical purpose.

None of the Standard's sections or requirements provide an express permission for the addition or use of caffeine in these foods.

Labelling – all foods - declared in the statement of ingredients

Caffeine must be declared in the statement of ingredients if and when present in a food for sale as an ingredient. If caffeine is used as food additive (where permitted – see above), the Code requires that it must be listed in the statement of ingredients as caffeine

Relevant Code provisions: 1.1.1—10(8), 1.2.1—8(1)(e), 1.2.4—3

1.1.1—10(9), 1.2.4—7(6)

Labelling – all foods – claims about caffeine in food products

Standard 1.2.7 prescribes what nutrition content claim or health claims can be made in relation to food.

The Standard does not expressly permit such claims to be made about caffeine (where permitted by the Code to be present in food).

Nor does the Standard expressly prohibit nutrition content claims or health claims being made about caffeine in a food.

The Standard does restrict when and how any such claims could be made.

If industry ever sought to make a nutrition content claim about caffeine, the claim could only state that the food (a) contains or does not contain caffeine; (b) contains a specified amount of caffeine; a combination of (a) and (b).

Similarly, a health claim about caffeine (e.g., 'improves mental performance') can only be made if the:

- food to which the claim relates is not a special purpose food and is a food is eligible to make a health claim, based on its nutrient profile; and
- particular manufacturer or seller has established a relationship between caffeine and the claimed health effect via systematic review conducted in a prescribed manner and had notified that fact to FSANZ in accordance with the Standard.

Relevant Code provisions: 1.1.1—10(8) and (9), 1.2.7—12, 1.2.7—13, 1.2.7—18, S4—3, S4—4, S4—5.

Appendix E: Imported food legislation and management of caffeine products at the border

Legislation

Foods imported into Australia are subject to requirements under the *Biosecurity Act 2015* to address biosecurity concerns and the *Imported Food Control Act 1992* (IFC Act) for compliance with Australian food standards and the requirements of public health and safety. Under the IFC Act, importers are legally responsible for complying with the standards that apply to their products to ensure they are safe and suitable for their intended use.

Section 16 of the IFC Act provides for the department to administer the Imported Food Inspection Scheme (IFIS). The *Imported Food Control Regulations 1993* sets out how the IFIS operates including the rates that foods are referred for inspection. For the operation of the IFIS, foods are either classified as risk food and are scheduled in the *Imported Food Control Order 2001* or are surveillance food.

Orders to classify food are made by the Minister based on risk advice from Food Standards Australia New Zealand (FSANZ). Food may be classified as risk food if FSANZ advises that the food has the potential to pose a medium to high risk to public health. The requirement for consultation with FSANZ on the risk classification of a food is outlined in Section 17 of the IFC Act.

Imported Food Inspection Scheme

Imported food is monitored for safety and compliance with Australia's food standards through a risk based inspection scheme, the Imported Food Inspection Scheme. Food is referred for inspection under the IFIS based on internationally agreed tariff codes. The rate at which food is referred for inspection depends on whether it is risk or surveillance food and its history of compliance. Food classified as compliance agreement food (food imported under a Food Import Compliance Agreement that is subject to audit) and most food from New Zealand (with the exception of beef and beef products, ready to eat cassava chips and seaweed-brown only) is not referred for inspection.

Risk food

Risk food is initially inspected and tested at a rate of 100 per cent of consignments. Once five consignments have passed consecutively, the inspection rate may be reduced to 25 per cent. The inspection rate is reduced to 5 per cent after a further 20 consecutive passes. A compliance history is developed for a risk food based upon a specific combination of producer, country of origin and tariff code.

Surveillance food

Surveillance food is referred to the IFIS randomly using electronic profiles in the Integrated Cargo System. Five per cent of a food is referred for inspection irrespective of the importer, producer or the country of origin of the food.

Holding Orders

Section 15 of the IFC Act provides for the department to apply a holding for a surveillance food that:

-
- has failed to comply with Australian standards,
 - is subject to a food recall or other incident and it is suspected it would not comply with Australian standards; or,
 - there is evidence of a food safety issue with the food.

It ensures future comparable consignments (same product, producer and country of origin) of a failed food are referred for inspection to ensure the reason that the food failed has been rectified.

A holding order remains in place until a history of compliance can be demonstrated, usually after five consecutive passes.

Management of caffeine products under IFIS

The department considers four standards in relation to food likely to contain caffeine:

- Standard 2.6.2 Non-alcoholic beverages and brewed soft drinks
- Standard 2.6.4 Formulated caffeinated beverages
- Standard 2.9.3 Formulated meal replacements and formulated supplementary foods
- Standard 2.9.4 Formulated supplementary sports foods.

Foods under these standards are surveillance foods and are inspected for compliance via product presentation and labelling checks against relevant standards in Chapter 1 and Chapter 2 of the Code, as specified in instructional material.

Prior to this year food labels were checked for caffeine and products failed where Schedule 15 or the relevant standard in Chapter 2 did not permit it based on the assumption that if caffeine was not specifically listed then it was not permitted.

Caffeine is not currently included in the list of additives to check because it became evident that inspection officers are not able to determine from the label whether caffeine had been added to perform a technological function as a food additive or added as an ingredient, on which the Code is silent. This is particularly the case for formulated foods.

Appendix F: Regulation of caffeine internationally

Pure and highly concentrated caffeine products

United States of America (USA)

In a statement dated April 2018¹², the US Food and Drug Administration (FDA) noted that many products consisting of only or primarily pure or highly concentrated caffeine are sold as dietary supplements. They consider some such products to be adulterated under the *Federal Food, Drug, and Cosmetic Act 1988* (FD&C Act), because they are dietary supplements that present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labelling or, if no conditions for use are suggested or recommended, under ordinary conditions of use.

The FDA issued 'guidance' stating it considers the following products to be 'adulterated' for the purposes of the FD&C Act: Powdered Dietary Supplements and Liquid Dietary Supplements containing pure or highly concentrated powdered caffeine and that are sold in bulk such that the consumer is required to separate out a safe serving from a potentially lethal amount.

The FD&C Act provides that a food is 'adulterated' for its purposes if, among other things, it contains a dietary ingredient that presents a **significant or unreasonable risk of illness or injury** under:

- (a) the conditions of use recommended in labeling
- (b) ordinary conditions of use if no conditions of use are suggested or recommended in labelling.

The FD&C Act prohibits interstate commerce of adulterated products.

US regulators also have enforcement tools in relation to adulterated food, e.g, seizure and destruction, injunctions preventing manufacturing or distribution or requesting a recall. Enforcement action is usually preceded by a Warning Letter from FDA to the manufacturer or distributor of the adulterated product. The Guidance states that Warning Letters had been issued for various products.

The FDA guidance states that the following are not considered to be adulterated:

- A. Dietary supplements sold in solid dosage forms, such as tablets or capsules that do not provide an excessive amount of caffeine per item. Products in these forms eliminate the need for a consumer to accurately measure the appropriate serving.
- B. Dietary supplements containing powdered or liquid caffeine (either diluted or undiluted) that are sold in premeasured packets or containers, with each premeasured unit containing an amount of caffeine that is not excessive. Products that are sold in pre-measured quantities eliminate the need for a consumer to measure the appropriate amount.
- C. Bulk powdered or liquid caffeine dietary supplement products that have been significantly diluted to low enough concentrations of caffeine, such that a reasonably

¹² Available at <https://www.federalregister.gov/documents/2018/04/16/2018-07836/highly-concentrated-caffeine-in-dietary-supplements-guidance-for-industry-availability> and <https://www.fda.gov/food/dietary-supplement-products-ingredients/pure-and-highly-concentrated-caffeine> Accessed 6 August 2019

foreseeable measurement error, misreading of the directions, or misunderstanding about the nature of the product.

Canada

Pure and highly concentrated caffeine products are permitted for retail sale. Caffeine shots (based on a specified size limit of a package containing 90 mL or less (or up to 125 mL depending on representation)), caffeine pills and caffeine powder typically used as a sports supplement are regulated as licensed natural health products under the Natural Health Products Regulations¹³. Registered caffeine-containing natural health products are listed on an on-line database¹⁴ by Health Canada.

The regulations have a general requirement for certain information to be included on a label of a natural health product, including each medicinal ingredient (such as caffeine), the recommended use or purpose, recommended dose, recommended duration of use (if any) and any risk information.

European Union

Caffeine is added as an ingredient to food supplements¹⁵, in which it is often used in combination with synephrine mainly for weight loss and enhanced sports performance.

It is the responsibility of the competent authorities of the Member States to classify a product taking into account its characteristics (e.g. whether a pure caffeine powder is a food supplement or medicine).

Food supplements are regulated under [Directive 2002/46/EC](#). Member States may develop regulation to implement this Directive. This Directive does not include compositional rules for caffeine. There is no permission to add caffeine as a flavouring to food supplements. In the absence of EU harmonised rules, national rules setting out which substances may be used and their conditions of use, may exist.

The amount of the substances with a nutritional or physiological effect (such as caffeine) present in food supplements shall be declared on the label as well as the portion of the product recommended for daily consumption and a warning not to exceed the stated recommended daily dose (the Directive requires the setting of maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer). A statement to the effect that the products should be stored out of the reach of young children is also required.

The Commission, on its own initiative or at the request of a Member State, can prohibit, restrict or put under Union scrutiny the use of other substances added to foods (including

¹³ Available at <https://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/> Accessed 6 August 2019

¹⁴ <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/applications-submissions/product-licensing/licensed-natural-health-products-database.html> Accessed 6 August 2019

¹⁵ **food supplements** means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities

food supplements). Caffeine has not been prohibited, restricted or put under scrutiny to date¹⁶.

Other foods containing caffeine

United states of America (USA)

In the USA, additives such as caffeine must be used in accordance with food additive regulation which specifies the conditions under which it must be used. However, such regulation is not needed if the substance is 'generally recognized as safe' (GRAS) (i.e. substances generally recognised to be safe by qualified experts)¹⁷. The FDA Code of Federal Regulations¹⁸, states that caffeine is GRAS when used in cola-type beverages and that the level of caffeine in these types of beverages must not exceed 0.02 per cent (i.e. 200 ppm).

Caffeine may also be used as an ingredient in other foods provided it has been determined as GRAS for its intended use in those foods. To date, no GRAS determinations for caffeine have been located via an internet search and there are none listed on the USA inventory of GRAS notices, except for one pending for *Ilex guayusa* leaf extract¹⁹.

Any food that contains added caffeine must have caffeine listed as an ingredient, but the actual quantity of caffeine does not have to be stated on the label. There are no other labelling requirements specifically for caffeine in the USA²⁰.

Canada

The addition of caffeine to food is regulated as a food additive. Carbonated soft drinks can contain caffeine, i.e. cola type beverages up to 200 ppm and non-alcoholic carbonated water-based flavoured and sweetened beverages other than cola type beverages up to 150 ppm²¹. Requests to add caffeine to foods such as snacks have not been accepted to date (personal communication).

As a food additive, caffeine would need to be declared in the list of ingredients²². No quantitative labelling is required however manufacturers are encouraged to label the amount of caffeine per stated serving size²³. This does not apply to foods/ingredients that are well known sources of caffeine (e.g. coffee, tea and chocolate). There is no regulatory requirement to identify the presence of or amount of caffeine for natural sources of caffeine.

¹⁶ https://ec.europa.eu/food/safety/labelling_nutrition/vitamins_minerals_en

¹⁷ <https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras> Accessed 6 August 2019

¹⁸ 21CFR182.1180 available at

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=182.1180> Accessed 6 August 2019

¹⁹ GRAS notices inventory is available at

<https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices>

²⁰ Leah S Rosenfeld, Jeremy J Mihalov, Susan J Carlson, Antonia Mattia, 2014. Regulatory Status of caffeine in the United States. Nutrition Reviews, Volume 72, Issue suppl 1, 1 October 2014, pp 23-33

²¹ List of Permitted Food Additives with Other Accepted Uses (Lists of Permitted Food Additives) available at <https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/8-other-accepted-uses.html> incorporated by reference in the [Marketing Authorization for Food Additives with Other Accepted Uses](#), enabled by the Food and Drugs Act. Accessed 22 July 2019

²² Food and Drug Regulations B.01.008 available at https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-5.html#docCont Accessed 22 July 2019

²³ Preliminary Guidance for Industry on the Labelling of Caffeine Content in Prepackaged Foods (March 2010) available at <https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/preliminary-guidance-industry-labelling-caffeine-content-prepackaged-foods-march-2010.html> accessed 22 July 2019

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

Caffeinated products that are pre-packaged, ready-to-consume, in a container containing 90 mL or less (or up to 125 mL depending on representation, as the typical container size for food beverages is 125 mL), and meant to be consumed in a single dose, shall be classified as natural health products.

Caffeinated energy drinks are also regulated as a food (before 2011 they were regulated as a natural health product). The regulatory requirements for these drinks have not yet been finalised as there are some outstanding information gaps. All caffeinated energy drinks are therefore still being regulated under the Temporary Marketing Authorization (TMA) framework²⁴. There are certain eligibility criteria associated with the TMA. The caffeine content of caffeinated energy drinks can be between 200-400 ppm. Alcoholic versions cannot be sold. Caffeinated energy drinks must be labelled with:

- a statement that they have a high caffeine content
- a quantitative declaration of total caffeine from all sources
- the statements:
 - Not recommended for children, pregnant or breastfeeding women and individuals sensitive to caffeine.
 - Do not mix with alcohol.
- a statement regarding the maximum number of containers/servings per day. This limit on the number of containers/servings must not result in the daily maximum limit being exceeded for any added vitamins, minerals or amino acids.

European Union

The use of caffeine as a flavouring substance in food is subject to restrictions of use in certain food categories (dairy products and analogues 70 mg/kg, edible ices 70 mg/kg, confectionery 100 mg/g, non-alcoholic beverages 150 mg/kg)²⁵.

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

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

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

²⁴ TMA letters are regulatory instruments that allow for non-compliant foods that meet all the requirements of a TMA to be sold before the regulatory amendments are made. The purpose of the TMA is to gather specific data that will support an amendment to the *Food and Drug Regulations*. <https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/category-specific-guidance-temporary-marketing-authorization-caffeinated-energy-drinks.html#s5.3.3>

²⁵ https://webgate.ec.europa.eu/foods_system/main/index.cfm?event=substance.view&identifier=2452

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

In 2018 the UK government consulted on ending the sale of energy drinks to children²⁶. According to media reports (July 2019), the government has confirmed it will ban the sale of energy drinks to children under 16.

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

²⁶ <https://consultations.dh.gov.uk/obesity/sale-of-energy-drinks-to-children/>