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[129–20]

Call for submissions – Urgent Proposal P1054 Pure and highly concentrated caffeine products - Assessment of the Approved Variation

On 12 December 2019, the Food Standards Australia New Zealand (FSANZ) Board approved a variation to the Australia New Zealand Food Standards Code (the Code) after considering an urgent proposal to prohibit the retail sale of pure and highly concentrated caffeine food products.

Under the urgent proposal provisions, FSANZ has assessed the resulting variation and is calling for submissions to help FSANZ decide whether to reaffirm the variation or to prepare a proposal to amend or repeal the variation.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

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

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

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

DEADLINE FOR SUBMISSIONS EXTENDED TO: 6pm (Canberra time) 11 September 2020

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

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 5423

Food Standards Australia New Zealand
PO Box 10559

KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

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Supporting documents

The [following documents](#) which informed the assessment of this Proposal are available on the FSANZ website:

Final Consideration Report – Urgent Proposal P1054 – Pure and highly concentrated caffeine food products.

SD1 Risk and technical assessment – Urgent Proposal P1054 – Pure and highly concentrated caffeine products.

Executive summary

On 12 December 2019, the FSANZ Board approved a variation (the variation) to Standard 1.1.1 of the Australia New Zealand Food Standards Code (the Code) to prohibit the retail sale of pure and highly caffeinated food products.

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

The variation was prepared and approved as part of an Urgent Proposal (P1054 – Pure and highly concentrated caffeine products) under Sub-Division A of Division 4, Part 3 of the *Food Standards Australia New Zealand Act 1991* (the Act).

The Act requires FSANZ to assess the approved variation within 12 months and decide whether to:

- reaffirm the decision to approve the variation, or
- prepare a proposal to develop a further variation (i.e. to repeal or amend the variation).

The Act requires FSANZ to call for public submissions after making its assessment, but before making the above decision.

FSANZ has completed its assessment of the approved variation in accordance with the Act. That assessment has confirmed FSANZ's initial risk assessment in 2019 that the sale of pure or highly concentrated forms of caffeine to consumers poses an immediate and acute risk, as demonstrated by the tragic death in NSW. Having regard to the evidence and the statutory assessment criteria, the FSANZ assessment remains that the approved variation, and its express prohibition on the retail sale of pure and highly caffeinated food products, was warranted given that immediate and acute risk.

FSANZ's assessment and its 2019 initial risk assessment both identified broader issues relating to caffeine's use and levels across the general food supply, particularly in relation to sensitive subpopulations (such as children, pregnant or lactating women and individuals sensitive to caffeine). Neither the approved variation nor this urgent proposal were intended to address these broader issues. Nor could they given the restraints imposed by the Act on urgent proposals.

Therefore, FSANZ's preferred option is to move now to examine the levels of caffeine in the general food supply, with a focus on sensitive subpopulations and on whether additional measures are required in order to protect the latter and public health and safety. To that end, FSANZ's preferred option is to prepare a proposal under the Act.

The prohibition on pure and highly concentrated caffeine food products would remain in place pending the outcome of the separate proposal process.

FSANZ now calls for submissions on whether to prepare a proposal to amend the variation to Standard 1.1.1., reaffirm, or prepare a proposal to repeal the variation.

1 Introduction

1.1 Background

In August 2019, FSANZ provided a report to Australian Ministers (the Ministers' report) that made five recommendations concerning the safety of pure and highly concentrated caffeine food products.¹ This report followed FSANZ's review of caffeine regulations and consumer warnings in response to the death of a young man in New South Wales attributed to acute caffeine toxicity associated with the consumption of a caffeine powder.

The first recommendation was that FSANZ develop and declare as urgent a proposal to amend the Australia New Zealand Food Standards Code (the Code) to prohibit the retail sale of pure and highly concentrated caffeine food products due to the unacceptably high risk for consumers and a need to act quickly to protect public health and safety. The proposal was prepared under FSANZ's urgent legislative provisions.

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

In December 2019, for the reasons detailed in the [Final Consideration Report](#), the FSANZ Board approved a variation to the Code to prohibit the retail sale of pure and highly concentrated caffeine food products. That is, of foods in which total caffeine is present in a concentration of 5% or more (if the food is a solid or semi-solid food) or 1% or more (if the food is a liquid food). The approved variation took effect on 12 December 2019 in Australia and on 3 February 2020 in New Zealand, and is at Attachment A.

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

The approved variation was not, and is not, intended to address broader issues related to the use of or presence of caffeine in food more generally.

FSANZ is reviewing the approved variation to decide whether it should be affirmed, repealed, or amended. This review must be completed by 12 December 2020 (within 12 months of approval).

FSANZ has now completed its assessment of the approved variation for the purposes of that review.

1.2 The approved variation and other relevant standards

1.2.1 The approved variation

Standard 1.1.1—10 of the Code sets out requirements relating to food for sale. The approved variation inserted a new provision into section 1.1.1—10 to prohibit total caffeine present in a concentration of 1% (1 000 mg/100 mL, liquid form) or 5% (5 000 mg/100g, solids and semi-solid foods, such as powders and gels) or more in the product presented at retail sale (unless that sale or presence was expressly permitted by the Code).

There was no exemption for naturally occurring sources of caffeine in the prohibition.

¹ <https://www.foodstandards.gov.au/Documents/CaffeineReport2019.pdf>

The current permissions in the Code relating to the use of caffeine as an ingredient in formulated caffeinated beverages and as a food additive in cola beverages is unchanged. These current maximum limits are lower than the new limits.

1.2.2 Summary of the Code provisions for caffeine

The regulatory regime governing caffeine is detailed in FSANZ’s report to Ministers. The following table is a summary of the relevant Code provisions.

Table 1: Code provisions for caffeine in food

Product	Current risk management/amount in food
<p>Solid and semi-solid foods</p> <p>Liquid foods</p>	<p>The Code provides that unless expressly permitted, a food for retail sale cannot be a food that contains caffeine in a concentration of 5% or more of the food for sale, if that food is a solid or a semi-solid food; or 1% or more of the food for sale, if that food is a liquid.</p> <p>An example of a semi-solid food is a gel.</p>
<p>Any food containing caffeine as an ingredient</p>	<p>A requirement to declare added caffeine (as caffeine) in the ingredient list, whether added as a flavouring substance or otherwise (subsection 1.2.4—7(6)).</p>
<p>Formulated beverage</p>	<p>The Code expressly prohibits the presence of caffeine in formulated beverages (sections 1.1.2—3 and 2.6.2—2).</p>
<p>Formulated caffeinated beverages (energy drinks)</p>	<p>The Code restricts the amount of caffeine in formulated caffeinated beverages (maximum of 320 mg per litre) (section 2.6.4—3).</p> <p>The Code requires mandatory labelling advisory statements that state that the food contains caffeine and is not recommended for children (no defined age), pregnant or lactating women and individuals sensitive to caffeine (subsection 2.6.4—5(3)).</p> <p>Labels must declare the maximum number of serves per day that should be consumed (based on content of certain nutrients rather than caffeine) (subsection 2.6.4—5(3)).</p> <p>Labels must declare the amount of caffeine (in mg) per serving and per 100 mL (subsection 2.6.4—5(1)).</p>
<p>Formulated supplementary sports foods (e.g. pre-workout supplements, protein powders)</p>	<p>May be regulated as either a food or NZ supplemented food or a therapeutic good depending on whether it meets the definition of a food in the FSANZ Act, or the definition of a therapeutic good in the Therapeutic Goods Act 1989 (see section 1.6 below).</p> <p>No express permissions for caffeine in formulated supplementary sports foods in the Code.</p> <p>Standard 2.9.4 currently under review in Proposal P1010 (Formulated Supplementary Sports Foods) – caffeine and labelling to be considered as part of this.</p>

Cola type drinks	The Code restricts the amount of caffeine if used as a food additive which must not exceed 145 mg/kg (Table to section S15—5, food class 14.1.3.0.2 – Cola type drinks). Labelling advisory statement ‘contains caffeine’ required (Table to section S9—2).
Food containing guarana or extracts of guarana	Labelling advisory statement ‘contains caffeine’ required (Table to section S9—2).
Flavourings permitted at GMP	Caffeine is prohibited from being included as a ‘permitted flavouring substance’. Therefore, any food categories in the table to section S15—5 allowing ‘additives at GMP’ or ‘Permitted flavouring substances’ are not permitted to contain caffeine within any flavouring preparation added to these food categories (Tables to sections S15—5 and S16—2, see entries for Permitted flavouring substances).

In summary, taking into account the approved variation:

- The Code does not expressly prohibit the addition or use of caffeine in food, apart from the exceptions noted below:
 - caffeine must not be present in a food for retail sale at a concentration of: 5% or greater if a solid or semi-solid food; or 1% or greater if the food is a liquid food
 - caffeine must not be added to formulated beverages
 - caffeine must not be part of a flavouring preparation (except for cola beverages) therefore where food categories listed in the table to section S15 are permitted to contain ‘additives at GMP’ or ‘permitted flavouring substances’, they must not contain caffeine as part of a flavouring preparation.
- There is no other express provision in the Code that prohibits caffeine’s use in, or addition to, any or all food.
- The Code expressly permits caffeine for use in cola type drinks (if used as a food additive) and in formulated caffeinated beverages as a stimulant. In both cases, this use is subject to compositional (including maximum permitted levels) and labelling requirements.
- To the extent that pure and highly concentrated caffeine food products are novel foods for the purposes of the Code, their retail sale as a food and their presence as an ingredient or component in a food for retail sale would be prohibited by the Code and State and Territory food laws. The status of pure and highly concentrated caffeine food products as a novel food remains untested by food regulators and the courts.
- The Code imposes prohibitions on the use of substances used as food additives, processing aids and nutritive substances, unless expressly permitted. These prohibitions, coupled with the absence in the Code of an express permission for caffeine’s use as a food additive, a processing aid or a nutritive substance, 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 other than in cola type drinks

- caffeine cannot be used in food as a processing aid or as a nutritive substance.

As explained in FSANZ Final Consideration Report, these prohibitions apply only to substances that fall within the Code's definition of used as a food additive, a processing aid or a nutritive substance.

1.3 Imported food into Australia

Foods imported into Australia are subject to requirements under 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 ensuring the foods they import comply with the standards that apply to their products and do not pose a risk to human health.

The IFC Act provides for the Department of Agriculture, Water and the Environment (DAWE) to administer the Imported Food Inspection Scheme (IFIS). The *Imported Food Control Regulations 2019* 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 2019* or are surveillance food.

FSANZ provides advice to DAWE on whether imported foods present a potential medium or high risk to public health. Orders to classify food as risk food are made by the Minister with consideration to FSANZ advice. Following FSANZ's amendment to the Code approved in December 2019, the Imported Food Control Order 2019² was amended to classify pure and highly concentrated caffeine products as risk food.³

1.3.1 Management of caffeine products under IFIS

Food likely to contain caffeine is inspected for compliance via product presentation and labelling checks against relevant standards in Chapter 1 and Chapter 2 of the Code.

1.3.2 Imported pure and highly concentrated caffeine food products

DAWE targets imported food by applying profiles in the Integrated Cargo System to food tariffs. Data shows that pure caffeine is imported under the Chapter 29 – Organic Chemical tariff for 'Caffeine and its salts'. If the products imported under this tariff are identified as retail-ready, they will be referred to the department for inspection.

1.4 Food imported into Australia from New Zealand

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

Clause 1.9 of the NZ SFS, permits caffeine to be added to a supplemented food for any purpose other than as a food additive, so long as the label includes: (a) an advisory statement that the food contains caffeine and is not recommended for children, pregnant or lactating women, or individuals sensitive to caffeine; and (b) the average quantity of caffeine

² <https://www.legislation.gov.au/Details/F2020C00121>

³ <https://www.agriculture.gov.au/import/goods/food/notices/ifn21-19>

per serve and the average quantity of caffeine per 100 mL or 100 g in the nutrition information panel.

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

The NZ SFS provides that specific provisions of the Code do not apply or are modified in their application to supplemented food in New Zealand. The Standard currently states that paragraphs 1.1.1—10(5)(b), (6)(b) and (f) of the Code do not apply to supplemented food. As such, all other provisions of section 1.1.1—10 of the Code do apply. This means that the new provision regarding caffeine in section 1.1.1—10 of the Code applies to supplemented food.

1.5 International approaches for regulating caffeine

There is no consistent approach to the regulation of products containing caffeine for sale to consumers in the United States of America (USA), Canada and the European Union as outlined in Table 2 below.

Table 2: International regulation of caffeine

	Pure and highly concentrated caffeine	Foods with added caffeine	Foods with naturally occurring caffeine
USA	Some products consisting of only or primarily pure or highly concentrated caffeine considered to be adulterated and hence sale prohibited ^a .	Caffeine is permitted in cola-type beverages at a maximum level of 0.02%. ^b No labelling requirements specifically for caffeine. ^b	No compositional limits or labelling requirements specifically for caffeine. ^b
Canada	Permitted for retail sale. Regulated as licensed natural health products under the Natural Health Products Regulations ^c . 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 (150-200 ppm) ^d . Specific labelling requirements for caffeinated energy drinks ^e .	No compositional limits or regulatory requirement to identify the presence of or amount of caffeine for natural sources.
European Union	Added as an ingredient to food supplements. The European Commission Directive 2002/46/EC relating to food supplements does not include compositional limits but EU member states may develop these. Labelling requirements for recommended daily consumption. ^f	Use of caffeine as a flavouring substance in food is subject to restrictions of use in certain food categories ^g . No compositional rules if added for a nutritional or physiological effect ^h however member states may develop these. Specific warnings required for caffeine. The actual caffeine content must also be on the label ⁱ .	Specific warnings required for some foods, excluding beverages based on coffee, tea or coffee or tea extract where the name of the food includes the term 'coffee' or 'tea'. ⁱ

a USFDA 2018; b USFDA 2020; c Canada 2003; d Canada 2020a; e Canada 2020b; f European Commission 2002; g European Commission 2018; h European Commission 2006; i European Commission 2011

1.6 Other issues: food-medicine interface in Australia

The regulation of caffeine in Australia falls within what is known as 'the food-medicine interface'. Generally a product that is swallowed will be regulated either as a therapeutic good or a food. Often, claims made about a product or the appearance of the product may suggest that it is a therapeutic good. However, the fact that certain claims are made about a product does not automatically make it a therapeutic good. Nor does the form of the product (capsules or powders) or if it is labelled as a 'dietary supplement'.

The potential regulatory overlap between certain foods and therapeutic goods at the 'food-medicine interface' means regulators, manufacturers and importers need a way to determine whether the Therapeutic Goods Act 1989 (TG Act) or State or Territory food legislation covers particular products. This is determined on a product by product basis via the food-medicine interface tool administered by the Therapeutic Goods Administration (TGA). A product cannot simultaneously be both a food and a therapeutic good in law.

Due to this complexity, FSANZ and the TGA agreed as part of the original proposal, that a two-pronged approach, managing caffeine as both a food via the Code and as a therapeutic good via the TG Act would best mitigate the potential risks. Under the urgent proposal and this full assessment, this approach was considered the most pragmatic way to manage acute toxicity risks.

1.6.1 Action taken by the Therapeutic Goods Administration

Listed medicine ingredients

Following the Ministerial request to review pure and highly concentrated caffeine products, the TGA amended the listed medicine ingredient requirements by the [Therapeutic Goods Amendment \(Permissible Ingredients\) Determination \(No. 1\) 2019](#). The new requirements specify that listed medicines which are undivided preparations (such as bulk powders) must not contain a concentration of caffeine greater than 4% (immediately – September 2019) and transitioning to not greater than 1% (by 2 March 2021). Divided preparations (such as tablets and capsules) must not contain a concentration of caffeine greater than 33%. For both types of preparations, the maximum recommended daily dose must not provide more than 400 mg of total caffeine from all ingredient sources, and a maximum dose of 100 mg per three hours is stipulated. The existing 100 mg maximum daily dose limit for caffeine as an individual ingredient continues to apply. 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.

This determination addressed the risks posed by high consumption of caffeine and other ingredients that contain the chemical caffeine as a component, in therapeutic goods entered in the ARTG.

Poisons standard

The [Standard for the Uniform Scheduling of Medicines and Poisons](#) (SUSMP or Poisons Standard) consists of decisions regarding the classification of medicines and poisons into Schedules for inclusion in the relevant legislation of States and Territories. Medicines and poisons are classified into Schedules according to the level of regulatory control over access to the poison required to protect public health and safety. Some of the substance restrictions in the schedules only apply above a certain quantity (this includes caffeine, as below).

On 1 June 2020, the [Poisons Standard \(No.2\) June 2020](#) amended schedules 4 and 6 of the Poisons Standard, to strengthen the regulation of caffeine in regard to pure or highly concentrated caffeine powder, due to the risk of poisoning⁴.

The Poisons Standard exempts nearly all food. 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 TG Act).

Caffeine, when the use is for internal therapeutic use⁵, has been specified as poison in Schedule 4 (prescription only medicines) of the Poisons Standard except:

- a) in divided preparations⁶ when labelled with a maximum recommended daily dose of no greater than 600 mg of total caffeine; or
- b) in undivided preparations with a concentration of 5% or less of caffeine and when labelled with a maximum daily dose of no greater than 600 mg of total caffeine.

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

The 5% concentration limits for caffeine specified mean that legitimate uses of caffeine are not inadvertently captured by the schedule 4 and schedule 6 entries (therefore both ARTG listed and registered products can continue to be marketed without scheduling restrictions). The TGA has considered that 5% or less was the appropriate concentration cut off from schedule 4 & 6. As the Code and the Poisons Standard sit side-by-side and do not operate in isolation, the alignment of these limits does not leave any gaps between the food and therapeutics regulation of high-concentration caffeine products.

Retail products, including sports supplements, containing Schedule 4 substances must only be supplied to consumers by pharmacists provided with a prescription.

Schedule 6 introduces changes that require strong label warnings when caffeine is above specified levels (i.e. POISON) and extensive safety directions educating consumers on its potential dangers and safe use.

As the Poisons Standard exempts the majority of food products, the amendments to the Code under P1054 in parallel with the scheduling amendments under the Poisons Standard are intended to prohibit high concentration caffeine products. The maximum limit of 5% in undivided preparation aligns with the Code.

⁴ Notice of final decisions to amend (or not amend) the current Poisons Standard, May 2020 - <https://www.tga.gov.au/scheduling-decision-final/notice-final-decisions-amend-or-not-amend-current-poisons-standard-may-2020>

⁵ The Poisons Standards contains the following definition:

"Therapeutic use" means use in or in connection with:

- a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in human beings or animals;
- b) influencing, inhibiting or modifying a physiological process in human beings or animals;
- c) testing the susceptibility of human beings or animals to a disease or ailment;
- d) influencing, controlling or preventing conception in human beings or animals;
- e) testing for pregnancy in human beings or animals; or
- f) the replacement or modification of parts of the anatomy in human beings or animals.

⁶ The Poisons Standards contains the following definition: **"Divided preparation"** means a preparation manufactured and packed as discrete pre-measured dosage units prior to sale or supply, and includes tablets, capsules, cachets, single dose powders or single dose sachets of powders or granules.

Section 7 declaration under the Therapeutic Goods Act 1989

Separate to the two-pronged approach of TGA and FSANZ to the regulation of caffeine, the TGA has undertaken to propose to make a declaration under the existing authority of section 7 of the TG Act that certain sports supplements are therapeutic goods. This proposal is still under development. A Regulation Impact Statement is being prepared for the section 7 proposal which will then be presented to Government for its decision.

Conclusion - how the TGA actions interface with the Code

For goods containing caffeine, including those on the food-medicine interface, a two-pronged approach means that a good is subject to caffeine limits, regardless of whether it is a therapeutic good or a food.

The Permissible Ingredient Determination means that goods sold as listed medicines are subject to caffeine controls, addressing the risks posed by high consumption of caffeine.

The changes to the Poisons Standard in relation to caffeine are consistent with the approved variation introduced under the urgent proposal.

FSANZ remains satisfied that a two-pronged approach is appropriate. This enables complete coverage of certain products containing caffeine, to the extent that there are no regulatory gaps.

1.6.2 The New Zealand Medicines and Medical Devices Safety Authority (Medsafe)

Dietary supplements are regulated under the Dietary Supplements Regulations 1985, which fall under the Food Act 2014 in New Zealand. Medsafe is responsible for administering the Dietary Supplements Regulations and the Ministry for Primary Industries (MPI) the Food Act. There are restrictions on certain ingredients (for example, they cannot contain certain substances listed in the First Schedule to the Medicines Regulations 1984 – meaning dietary supplements cannot contain ingredients that are scheduled as prescription medicines, restricted (pharmacist only) medicines or pharmacy-only medicines under the Medicines Act 1981.

Medicines are regulated under Medicines Act 1981. Caffeine is not currently classified (scheduled) under the Medicines Act, meaning no concentration limit applies if caffeine is contained in a medicine. However, the NZ Medicines Classification Committee (MCC) (under the Medicines Act 1981) reviews Australian classification changes, and therefore as caffeine has undergone scheduling changes in Australia, the same changes would be considered by the MCC.

1.7 Reasons and procedure for assessing the variation

The Act requires FSANZ to assess the variation within 12 months and decide whether to reaffirm the decision to approve the variation or to prepare a proposal to develop a further variation (i.e. to repeal or amend the variation). The Act also requires FSANZ to call for public submissions after making its assessment, but before making that decision.

1.8 Scope

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

A Working Group⁷ established by FSANZ agreed the availability of pure and highly concentrated caffeine food products for retail sale posed an unacceptably high risk and should be considered urgently and separately to other products containing caffeine (refer to Executive Summary of the FSANZ Report to Ministers).⁸

2 Summary of the assessment of the variation

2.1 Approach to review and full assessment of the approved variation

FSANZ must decide whether to prepare a proposal to amend the variation to Standard 1.1.1., reaffirm the variation to Standard 1.1.1 (available in Attachment A), or prepare a proposal to repeal the variation.

These matters are considered below.

2.2 Risk assessment

Caffeine has the technological function as a flavouring in many countries, including in Australia and New Zealand. In the Code, it is permitted to be added as a flavouring to cola type drinks. If used as a stimulant (not a food additive), it can be added to formulated caffeinated beverages to enhance mental performance. Regardless of the purpose of adding caffeine to food it is appropriate that it complies with a relevant specification in Schedule 3. One of the primary sources of specifications in Schedule 3 is the Food Chemicals Codex which contains a specification for caffeine.

FSANZ's risk assessment confirmed that there is an immediate and acute risk posed by the sale of pure or highly purified forms of caffeine to consumers. Ingestion of small amounts of these substances can result in severe health effects, including death.

For powders and other solid products containing caffeine, FSANZ has identified that less than or equal to 5% caffeine is not considered to pose an unacceptably high risk to

⁷ In developing its report to Ministers, FSANZ established a working group with representatives from Commonwealth agencies (the Department of Health, the Therapeutic Goods Administration (TGA) and the then Department of Agriculture), food regulatory authorities from the States and Territories and New Zealand's Ministry for Primary Industries and New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

⁸ <https://www.foodstandards.gov.au/Documents/CaffeineReport2019.pdf>

consumers. A caffeine concentration of 5% is slightly higher than the levels of caffeine typically found in instant coffee, and a heaped tablespoon of such a powder would contain approximately 825 mg caffeine, a dose which would be unlikely to cause severe health effects in healthy adults.

Accidental ingestion of liquid containing high concentrations of caffeine may occur more easily than with bulk powder products. FSANZ considers that for concentrated solutions of this type, a maximum level of 1% w/v caffeine is required to protect public health and safety. This value is based on the practical consideration that in order to dispense 100 mg caffeine, 10 mL of solution would be required.

The Risk Assessment therefore concluded that the maximum concentration of caffeine in powders or other solids should not exceed 5% w/w, and that the maximum concentration of caffeine in liquids should not exceed 1% w/v.

2.3 Risk management

FSANZ's assessment is that pure and highly concentrated caffeine food products are high risk and a significant health concern. Therefore, the intent, objective and decision by the FSANZ Board (December 2019) was to prohibit the retail sale of foods in which total caffeine is present in a concentration of 5% or more (if the food is a solid or semi-solid food) or 1% or more (if the food is a liquid food).

2.3.1 Specific risk management issues and matters considered

The Final Consideration Report⁹ (December 2019) details the assessment on which the approved variation was based and FSANZ's reasons for preparing and approving that variation.

FSANZ's approach to the assessment and the approved variation consisted of the following principles:

- to address acute exposure to pure and highly concentrated caffeine food products for Australian and New Zealand consumers by a prohibition on the retail sale of high risk food products to consumers
- enable consumers to continue to purchase and consume caffeinated food products such as instant coffee powder and other coffee forms, caffeinated beverages including energy drinks, tea, and chocolate
- not prevent purchase of ingredients containing caffeine for use by beverage and pharmaceutical manufacturers permitted to use or add caffeine to their products
- not impact most types of products that may also contain caffeine, such as conventional foods or therapeutic goods.

However, the timeframe and scope of the urgent proposal did not provide the opportunity to review the risks posed by caffeine more holistically and issues outlined below provide a potential reason to amend the variation in this Call for Submissions Report.

2.3.1.1 Sensitive subpopulations

Risks to sensitive subpopulations were identified and considered in FSANZ's initial assessment.

⁹ <https://www.foodstandards.gov.au/code/proposals/Pages/P1054.aspx>

In the Initial Consideration Report (1 November 2019) FSANZ assessed the risks of acute exposure to pure and highly concentrated caffeine food products and noted the following:

- EFSA and the US FDA concluded that a total caffeine intake of 400 mg/day (5.7 mg/kg bodyweight/day) is safe for most adults. However, EFSA recommends that pregnant women should not consume more than 200 mg/day.
- Formulated caffeinated beverages (including energy drinks) have permission for the addition of caffeine at levels prescribed by the Code. This includes mandatory labelling requirements that the food contains caffeine and is not recommended for children (no defined age), pregnant or lactating women and individuals sensitive to caffeine.
- Caffeine exposure from foods for sensitive subpopulations would be best assessed and managed as part of a broader review of caffeine across the whole food supply.

In 2015, the European Food Safety Authority (EFSA) concluded that for healthy adults and the elderly, single doses of caffeine of up to 200mg (approximately 2½ espressos or 4 cups of filter coffee) do not raise any safety concerns. For regular consumption, EFSA concluded that caffeine consumption up to 400mg over 24 hours is not likely to cause any harm to the adult consumer. For pregnant and breastfeeding women, daily caffeine consumption of up to 200mg is safe for the unborn child or breastfed infant¹⁰.

The Australian Department of Health suggests limiting intake during pregnancy to around three cups of coffee or six cups of tea a day (e.g. 300 mg of caffeine). Other caffeinated beverages (e.g. colas, energy drinks, green tea) should also be limited¹¹. Children should consume less than 100mg per day¹².

Pregnant women in New Zealand are advised to limit consumption of drinks containing caffeine with a maximum of six cups of tea or instant coffee, or three single espresso-style coffees daily¹³. Energy drinks and energy shots are not recommended due to high caffeine levels for children, young people or pregnant women.

Since the Initial Consideration Report and following consideration by the FSANZ Board in December 2019 (and agreement to the approved variation) FSANZ obtained data from Australian and New Zealand poisons information centres. This confirmed that toddlers, children and pregnant women are exposed to a range of sources of caffeine (coffee, tea, energy drinks, cola beverages, over the counter drugs and sports drinks) with accompanying reports of adverse health effects.

Concerns for sensitive subpopulations were identified when the Australia New Zealand Food Authority (now FSANZ) considered Application A394¹⁴ - Formulated Caffeinated Beverages (FCBs). Concerns in regard to sensitive subpopulations caffeine exposure led to controlling the maximum level of caffeine and other substances used in product formulation, and requiring a label statement that advises against consumption by children, pregnant and lactating women and caffeine sensitive people.

Another example in relation to caffeine exposure for sensitive subpopulations was FSANZ's previous assessment of application A334¹⁵. Although the Applicant formally withdrew this

¹⁰ <https://www.foodstandards.gov.au/consumer/generalissues/Pages/Caffeine.aspx>

¹¹ <https://www.health.gov.au/resources/pregnancy-care-guidelines/part-c-lifestyle-considerations/nutrition-and-physical-activity>

¹² <https://www.healthdirect.gov.au/caffeine>

¹³ <https://www.mpi.govt.nz/dmsdocument/3569/direct>

¹⁴ <https://www.foodstandards.gov.au/code/applications/Pages/applicationa394/index.aspx>

¹⁵ This Application was seeking permissions to add caffeine to other soft drinks at the same maximum level of 145 mg/kg as per the current permissions for Kola type beverages in the Code.

Application, the subsequent period (2000 onwards) led to a series of policy discussions on caffeine, which culminated in policy being issued by the Forum (4 April 2003) that addition of caffeine to other soft drinks was *not permitted*¹⁶. The focus of the policy was on sensitive populations such as children and intended to provide a mechanism for FSANZ to restrict Applications from industry seeking to broaden the use of caffeine into other soft drinks.

2.3.1.2 Conclusions

FSANZ assessment is that, for the reasons stated above, the decision to prohibit pure and highly concentrated caffeine food products was and is warranted. That said, it is apparent, having regard to the evidence and the statutory assessment criteria, that there is a need to consider wider issues, in particular the extent of the risk posed to sensitive subpopulations by caffeine in the food supply and whether and how any such risk should be managed.

FSANZ preferred option is therefore to prepare a proposal under section 55 for this purpose and to consider further variations to the Code. This approach may also be a pathway for to address recommendation 2¹⁷ in FSANZ review of pure and highly concentrated caffeine products, which is to consider a maximum limit on caffeine for foods in the general food supply. This could be progressed either under the new section 55 proposal or in conjunction with FSANZ's review (now underway) of Standard 2.9.4 (which covers sports foods).

2.3.2 Risk management options

FSANZ considered the following three risk management options:

Option 1: reaffirm the approved variation

This option consists of the following:

- *Reaffirm the amendment to standard 1.1.1—10(5) such that unless expressly permitted by the Code, food for retail sale cannot be a food that contains caffeine in a concentration of 5% or more of the food for sale (if the food for sale is a solid or semi-solid food) or 1% or more of the food for sale (if that food is a liquid)*
- *this amendment applies the concentration limits for caffeine to all foods for retail sale; and includes caffeine that occurs or is present naturally in the food for sale.*

This option addresses the acute and immediate risk of pure caffeine powders and highly concentrated caffeine food products that present an unacceptable risk to consumers. The accompanying risk assessment confirmed the concentration limits derived under the urgent proposal as appropriate for acute exposure to highly concentrated caffeine food products.

FSANZ has previously concluded that the Code does not prohibit the addition of a food additive (e.g. caffeine) to food for purposes other than used as food additive. Therefore, the key issue is whether the Code should prohibit the addition of caffeine, or more broadly food additives (other than when used as a food additive function) across the food supply; and then, only permit where warranted, rather than only expressly permit its addition to specific foods.

As the scope of this Proposal is the threat posed by pure and highly concentrated caffeine foods and liquid products, further work separate to this Proposal is needed to address the addition of caffeine to food, including consideration of a 'prohibit unless permit' approach. This will involve identifying if the Code requires amendment to state caffeine requires express permission, when added to food for purposes other than as a food additive

¹⁶ <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/consult-Addition-of-Caffeine-to-Foods>

¹⁷ Recommendation 2 was part of the August 2019 report to Ministers that made five recommendations concerning the safety of pure and highly concentrated caffeine food products.

Option 2: prepare a proposal to repeal the approved variation; meaning the measure is no longer warranted.

This option consists of the following:

- *do not reaffirm the amendment to standard 1.1.1–10(5), noting that this would not remove the approved variation until a separate proposal was prepared by FSANZ and the approved variation was repealed*
- *following repeal the Code would continue to operate as it did before the P1054 urgent measure was put in place.*

Repeal is not supported because of the following:

- a significant potential harm exists from these products, therefore, this option is unlikely to adequately ensure public health and safety
- costs to the government of future incidents and health treatments
- costs associated with unwinding the regulation at this stage
- no evidence has been identified suggesting that the approved variation, targeted at consumption of pure and highly concentrated caffeine products, is unwarranted
- in general, submitters to the initial assessment for P1054 were supportive of the prohibition above specific concentration limits
- the approved variation supports actions taken by the TGA to strengthen the regulation of caffeine, in particular for pure and highly concentrated products.

Option 3: prepare a proposal to amend and/or add to the approved variation.

This option consists of the following:

- *the current measure (prohibition on pure and highly concentrated caffeine products) would remain in place until such time as it is amended by a further variation developed by a new separate proposal. That new proposal must be prepared (but not completed) before 12 December 2020.*

The rationale is that, while the approved variation was and is warranted in terms of public health to address consumption of pure and highly concentrated caffeine food products, there is an apparent need to consider the risk posed by caffeine in the wider food supply to sensitive subpopulations and further amendment of the Code to address that risk.

FSANZ will consider options for amending the variation under the separate proposal.

Preferred option

FSANZ's assessment, for the reasons stated above, supports option 3 to prepare a proposal under section 55 of the Act for the development of a further variation of the Code.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. In relation to this urgent proposal, the call for submissions was notified through notification circulars, a media release, social media and updated web content. FSANZ also consulted with the Working Group established to assist in the initial review. Members included food regulatory authorities from the Australian Commonwealth, the Australian States and Territories, New Zealand's

Ministry for Primary Industries, and Medsafe.

Industry and key stakeholders were also notified of the release of the call for submissions through email.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this full assessment of the approved variation made under an urgent Proposal. Every submission on this proposal will be considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

2.4.2 World Trade Organization (WTO)

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

As WTO members, Australia and New Zealand are also obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade. The measure was notified in December 2019 after the public notice of the urgent measure. No submissions were received from member organisations.

2.5 FSANZ Act assessment requirements

FSANZ's options under the full assessment are to reaffirm the variation to Standard 1.1.1, available in Attachment 1, or to prepare a proposal to repeal or amend the variation. FSANZ has had regard to the following matters under section 99 and section 18 of the FSANZ Act.

2.5.1 Section 99

FSANZ's initial assessment was to prohibit the retail sale of pure and highly concentrated caffeine food products because of the high risk and significant health concerns for Australian and New Zealand consumers.

FSANZ's assessment is therefore that the intent of the prohibition on the retail sale of foods in which total caffeine is present in a concentration of 5% or more (if the food is a solid or semi-solid food) or 1% or more (if the food is a liquid food) should be retained in the Code. FSANZ is not aware of any reason to change that assessment or conclusion.

However, for the reasons stated elsewhere in this report, FSANZ's assessment is that alternative measures need to be considered and that a proposal should now be prepared for that purpose.

Subsection 99(2) of the Act requires FSANZ to have regard to certain specific matters when assessing the variation. These matters are considered below.

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

The purpose of this consideration is to determine the option that is likely to create the most benefit, on balance, for the community, government, and industry as a whole.

FSANZ concluded in the Final Consideration Report that the benefits of the approved variation were likely to outweigh the costs. FSANZ still considers that a prohibition is likely to

be economically preferred to repealing the measure, however amendments to the approved variation may assist to build on the net benefit and should be considered further.

FSANZ will undertake a new proposal process to assess the merits of amending the approved variation. The Office of Best Practice Regulation (OBPR) advised that a Regulatory Impact Statement (RIS) would be best practice to inform this assessment (email dated 19 May 2020, OBPR reference 25907).

The RIS that accompanies the new proposal will include regulatory analysis of options including reaffirming the approved variation, repealing the approved variation and suggested amendments.

Without detailed scoping of the potential options to be considered in the proposal, FSANZ is unable, at this stage, to determine which of these options is likely to generate the greatest net benefit to the community on balance. This assessment will be undertaken as part of the new proposal process.

However, given the new proposal seeks to address some of the costs identified through the consultation process, it is likely that amending the approved variation will be of greatest benefit to the community, on balance.

FSANZ's assessment is that proceeding with a proposal to examine alternatives to the approved variation is likely to result in an option that will have the greatest net benefit.

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

For the reasons provided in the full assessment, FSANZ is satisfied that a prohibition is the most cost-effective food regulatory measure to address the threat posed by pure or highly concentrated caffeine food products.

For the reasons explained above, FSANZ's preferred option is to prepare a new separate proposal. That proposal will allow further reconsideration of the costs and impact of the current approved variation and alternatives. During that process a full regulatory impact statement will be prepared.

c) all relevant New Zealand standards

In assessing this proposal, FSANZ has had regard to paragraph 99(2)(c) of the FSANZ Act, which requires FSANZ to have regard to any relevant New Zealand standards. The amendment made under the approved variation to Standard 1.1.1 of the Code applies in both Australia and New Zealand.

New Zealand food law includes the *New Zealand Supplemented Food Standard 2016*. How that Standard operates is discussed in section 1.4.1 above. The new provision in section 1.1.1—10 and its prohibition (or any amendment of the variation under the same section) will apply to supplemented food unless the New Zealand Government decides to amend the *New Zealand Supplemented Food Standard 2016* to dis-apply that provision.

d) any other relevant matters, including FSANZ's statutory objectives in standards development

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

The FSANZ Act requires FSANZ to have regard to the fact that the primary objective in standards development is the protection of public health and safety. FSANZ concluded that a prohibition as provided by amending the approved variation best addressed the threat posed by pure and highly caffeinated products for consumers of these products. However, the threat for sensitive and vulnerable subpopulations needs further consideration, as identified in previous sections of this report.

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

There are no proposed additional labelling measures being considered in this proposal (P1054) to protect health and safety of consumers from consuming pure and highly concentrated caffeine food products.

2.5.2.3 The prevention of misleading or deceptive conduct

The prohibition imposed by amending the approved variation protects consumers unaware of risks of consumption of pure and highly concentrated caffeine food products, thereby supporting the objective of prevention of misleading or deceptive conduct.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

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

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

There are no consistent international standards for caffeine, nor is there a consistent approach internationally for regulating caffeine (see section 1.5 above). The US FDA has issued guidance stating its position that the sale of certain pure and highly concentrated caffeine food products are prohibited under US food law because of the significant public health and safety risks they pose.

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

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

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

In December 2019, FSANZ made notifications under both the WTO Technical Barriers to Trade (TBT) and Application of Sanitary and Phytosanitary Measures (SPS) notification systems. The notifications were made after the public notice of the variation. No comments were received by WTO members.

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

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

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

The Forum (then convening as the Australia and New Zealand Food Regulation Ministerial Council) agreed to an amended Policy Guideline on the regulatory management of caffeine in the food supply in June 2014¹⁸.

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

¹⁸ The Policy Guideline is available at <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Caffeine-to-Foods>

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

It is unlikely that an update will be available for this assessment of the approved variation, as statutory time frames are in place. However, if the policy guideline is updated, it will provide valuable policy direction for FSANZ's future work on caffeine in the food supply.

3. References

Canada 2003, Natural Health Products Regulations, available at <https://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/> Accessed 19 May 2020

Canada 2020a 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> Accessed 20 May 2020

Canada 2020b [Category Specific Guidance for Temporary Marketing Authorization – Caffeinated Energy Drinks](#). Accessed 20 May 2020.

European Commission 2002, Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, available at https://ec.europa.eu/food/safety/labelling_nutrition/supplements_en, accessed 20 May 2020.

European Commission 2006, [Regulation \(EC\) No 1925/2006](#) of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. Accessed 20 May 2020

European Commission 2011 [Regulation \(EU\) No 1169/2011 of the European Parliament and of the Council](#) of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. Accessed 20 May 2020.

European Commission 2018 [Commission Regulation EU 2018/1482](#) of 4 October 2018 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards caffeine and theobromine. Accessed 12 May 2020.

USFDA 2018, [Guidance for Industry: Highly Concentrated Caffeine in Dietary Supplements](#) Accessed 19 May 2020.

USFDA 2020 [eCFR — Code of Federal Regulations](#) 21 CFR Accessed 19 May 2020.

Attachments

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

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



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

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

Dated 11 December 2019

A handwritten signature in black ink, appearing to read "Richard".

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

Note:

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

1 Name

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

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

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

3 Commencement

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

4 Transitional arrangements

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

Schedule

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

- (f) if the food is for retail sale—raw apricot kernels;
- (g) if the food is for retail sale—a food in which caffeine is present at a concentration of:
 - (i) 5% or greater—if the food is a solid or semi-solid food; and
 - (ii) 1% or greater—if the food is a liquid food.