Government of **Western Australia**
Department of **Health**

Department of Health Western Australia submission to:

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

---

Approved by: [redacted]
Managing Scientist - Food
Environmental Health Directorate
Public and Aboriginal Health
Department of Health Western Australia
Level 3, A Block, 189 Royal Street, EAST PERTH, WA 6004
PO Box 8172, PERTH BUSINESS CENTRE WA 6849
[redacted]

Date of Submission: 10 September 2020

The Department of Health WA (DOH) would like to thank Food Standards Australia New Zealand (FSANZ) for the opportunity to provide comment on Urgent Proposal P1054 – Pure and highly concentrated caffeine products – Assessment of the Approved Variation. The Environmental Health Directorate of the DOH has prepared this response.

In summary
As per, the DOH's previous submission on P1054, it remains concerned that the draft variation to the Australia New Zealand Food Standards Code (the Code) proposed in P1054:

- does not address concerns about concentrated caffeine products;
- does not provide regulatory certainty for purposes of compliance and enforcement;
- is inconsistent with the *Ministerial Policy Guideline for the Regulatory Management of Caffeine in the Food Supply,* which states that the regulatory management of caffeine in the food supply should:
  - be based on risk analysis ensuring consideration of the general population and taking into account vulnerable population groups, including children, adolescents, pregnant and lactating woman and caffeine sensitive consumers; and
  - consider exposure to caffeine from all dietary sources.
- is inconsistent with the current restrictions in place for caffeine in formulated caffeinated *beverages* (FCBs) *and kola beverages;*
- may pose a risk to public health and safety by increasing the amount and variety of food products containing caffeine in the food supply (the safety risk is not limited to subpopulations); and
- impacts on the ability to apply "unsafe" and "unsuitable" provisions of the *WA Food Act 2008* (the Food Act).

The DOH believes an alternative approach is to amend Standard 1.1.1 – 10 (6) which states '*Unless expressly permitted by this Code, food for sale must not have as an ingredient or a component, any of the following*:
(j) raw apricot kernels;'
(k) *insert 'caffeine' here*

This would mean that caffeine, unless expressly permitted in the Code, could not be added to food. The permission to use caffeine as a food additive in kola-type beverages, and as an ingredient in FCBs, would still apply. Food containing caffeine naturally would still be permitted in line with Standard 1.1.1 -10 (7) which states '*Subsection (6) does not apply to a substance that is in a food for sale, or in an ingredient for sale, by natural occurrence'*

The DOH is concerned that the options presented in P1054 have created the situation where neither option 2 or option 3 protects public health and safety. However, given the current conundrum, WA is prepared to support Option 3, with the proviso that the new proposal be prioritised and dealt with expediently.

Specific Issues of Concerns are as follows:

Application of the Food Act relating to "safe and suitable" food
The DOH is concerned that the draft variation to Standard 1.1.1 – 10 (5) will impact on the State's ability to apply the "unsafe and unsuitable" provisions of the Food Act.

FSANZ approach to restricting caffeine, while well intended, seems to have inadvertently created a permission; and indicates an acceptance that 5% caffeine in solid and semi-solid food, and 1% caffeine in liquid food, is a "safe" amount of caffeine, regardless of serving size. This makes it very difficult from an enforcement perspective to act on the basis that a product containing less than 5% in a solid or semi-solid (i.e. gel) food, or less than 1% caffeine in liquid food, is "unsafe" or "unsuitable", should the amount of caffeine in a serving size of a product exceeds what is deemed to be a reasonable level of caffeine to consume, i.e. the European Food Safety Authority (EFSA) suggests a maximum 200mg in a single serve for a person over the age of 18 years.

For the purposes of the Food Act (s.12) (1) a food is "unsafe" at a particular time if it is likely to cause physical harm to a person who might later consume it, assuming – (a) it was consumed subject to all processes that are relevant to its reasonable use; (b) nothing happened to it after a particular time and before being consumed by the person that would prevent it from being used for its reasonable intended use; and (c) it was consumed by the person according to its reasonable intended use. However (2), a food is not unsafe merely because its inherent nutritional or chemical properties cause, or its inherent nature causes, adverse reactions only in persons with allergies or sensitivities that are not common to the majority of persons.

In addition, the definition related to 'unsuitable' under the Food Act (s.13) (2), states that a food is not 'unsuitable' if it contains any matter or substance that is permitted by the Code.

Recently a caffeine energy shot product was presented for Food-Medicine Interface Assessment and discussed at a meeting of the Bi-national Food Safety Network, that contains 300 mg of caffeine in a 90 ml serve (approximately 0.33 %). Two serves of this product would equate to 600 mg of caffeine, which is 200 mg in excess of the reasonable daily amount of caffeine (from all sources), as per the EFSA advice, stating that a reasonable level of caffeine consumed by an adult is a maximum 400 mg caffeine per day from all sources. This energy shot product appeared to be presented as a Formulated Supplementary Sports Food (Standard 2.9.4), and while it did not comply with all of the compositional and labelling provisions of the Code, it did comply with the provisions for caffeine in Standard 1.1.1 – 10 (5). The DOH is concerned that the amount of caffeine in this type of product exceeded what the EFSA deems a reasonable maximum amount of caffeine (200 mg) in a single serve, and yet as the product meets the levels for caffeine permitted by Standard 1.1.1 – 10 (5) of the Code, the 'unsafe' and 'unsuitable' provisions of the Food Act would be difficult to apply. In any legal proceeding it would be up to the State to demonstrate beyond a reasonable doubt that the product was 'unsafe' or 'unsuitable' and in light of the permissions for caffeine in Standard 1.1.1 – 10 (5) of the Code, it is unclear as to how this could be done, without a human case of adverse consequence associated directly with a caffeinated product.

FSANZ has inadvertently created an express permission in the Code

- The amendment proposed to Standard 1.1.1 – 10 (5), which states '*Unless expressly permitted by this Code, food for sale must not be any of the following*: (g) *if the food is for retail sale – a food in which caffeine is present at a concentration of 5% or greater – if the food is a solid or semi-solid food; or 1% or greater – if the food is a liquid food'*, appears to provide an express permission, for the retail sale of food (any food) in which caffeine is present at a concentration of up to 5% in solid and semi-solid food, and up to 1% in liquid food.

- The DOH considers that it has always been the intention of the Code to restrict caffeine in the food supply, whereby express caffeine permissions only exist for FCBs (Standard 2.6.4) and kola beverages, when used as a food additive. There is no restriction on food where caffeine is present naturally.

- Additionally, the DOH is aware that under the Trans-Tasman Mutual Recognition Agreement, foods containing caffeine that comply NZ laws may be sold in Australia and that certain sports foods and caffeine shots seem to be in the Australian marketplace through this mechanism.

- It is noted that the Code revision amendments made in Proposal P1025, around the definition of a food additive have resulted in a new interpretation of permission, such that if caffeine is used as something other than a food additive, like a 'stimulant', then it would be permissible in a food. This Code revision was for the purpose of improving legal efficacy and for related purposes. The purpose of this the revision was to reduce uncertainty about the permissions to add substances to food that are in the current Code. It was not meant to change permissions for the addition of chemicals to foods. Any significant change to the Code for a broad permission addition for toxic chemicals as a stimulant to food would have required FSANZ to undertake appropriate regulatory processes under the *FSANZ Act 1991*.

- The DOH does not consider that it was the intention of the Code to permit caffeine to be added to food, outside where there is an express permission to do so. This approach would be more in line with the *Ministerial Policy Guidelines for the Regulatory Management of Caffeine in the Food Supply.*

- The August 2013, Food Regulation Standing Committee, *Policy Options Paper on the Regulation of Caffeine in Foods* (Options paper), described the regulations applying to caffeine in food in Australia, stating that prior to 2001 caffeine was permitted only in food naturally containing caffeine, and kola-type beverages, where used as a food additive for flavouring purposes. The Options Paper further states that in 2001, FSANZ amended to Code to permit the production and sale of energy drinks (FCBs). In 2013, the Options Paper identified that the Code permits the addition of caffeine to kola-type beverages, as a food additive; in food that naturally contains caffeine (tea, coffee, cocoa and guarana); and FCBs. The Options Paper further states that the Code is silent on whether or not caffeine can be present in 'Formulated Supplemented Sports Food' (Standards 2.9.4).

- The DOH does not consider FSANZ has had due regard to the *Ministerial Policy Guidelines for the Regulatory Management of Caffeine in the Food Supply* in the creation of the emergency Proposal (P1054).

Safety issues

- In P1054, Table 3 – Acute effects of caffeine in adults, recognises that 3000 mg of pure caffeine as potentially a lethal dose, while 5000 mg is a life-threatening dose of caffeine. The DOH is concerned that by allowing caffeine to be present at up to 5% (5000 mg/ 100 g) in food (solid and semi-solid, including gels) for retail sale, and 1% (1000 mg/ 100 g) in liquid food for retail sale, may pose a risk to health of the general population, particularly for vulnerable population

groups, including children, adolescents, pregnant and lactating woman and caffeine sensitive consumers.

- The DOH is also concerned that the draft variation proposed in P1054, to Standard 1.1.1 – 10 (5) of the Code, may result in more food products containing caffeine, entering the marketplace.

- Potentially, this could see caffeine present in a range of food (solid and semi-solid) at a concentration of up to 5% and for beverages at a concentration of up to 1%, including food for infants; processed cereal products, snack foods, beverages not meeting the definition of a FCBs, and alcoholic beverages. While the bitterness of caffeine may be a limiting factor in the amount that can be added to food and remaining palatable, the addition of sugar and/or intense sweeteners can serve to counteract this to some degree.

- The draft variation does not take into account the type of food and the manner in which the food is intended to be consumed. The Code is also silent on the reasonable amount of caffeine in single serving size. It would be easier to consume a higher volume of liquids containing up to 1% caffeine, than a food, such as dried instant coffee and tea. A pre-made beverage with caffeine present at a concentration of up to 1%, may be consumable as one serve. This would potentially mean an individual could consume a single serve of a caffeinated product and exceed what the EFSA deems to be the maximum reasonable amount of caffeine to consume in single serve, for an adult.

- It is also a concern that a food may contain a caffeine concentration of up to 5% in solid and semi solid food, and up to 1% in liquid food, without being required to provide an advisory statement on the label. FCBs (Standard 2.6.4) containing a maximum 0.032% caffeine are required to have a caffeine advisory statement on the label, yet food and beverages with a concentration of caffeine up to 1% are not required to carry an advisory statement.

- The DOH is not only concerned that there will be no requirement for the products containing added caffeine up to 5% in a solid or semi-solid food and up to 1% in a liquid food to carry any advisory statement (unless the product is a FCB), it is also concerned that there is no requirement to declare how much caffeine is present in the food product for retail sale. Therefore, how does a caffeine sensitive individual or even a general adult consumer gauge how much caffeine they have consumed in a serve, or per one day quantity.

- The DOH is concerned that aiming restrictions of high level caffeine products only at the retail (outlet) level, may not address the issue of pure and high caffeinated products being in the marketplace entirely. It is still not clear as to how consumers are sourcing/purchasing these concentrated form of caffeine powder/products i.e. who is purchasing them and from where (online for personal consumption and/or shared: or at retail and stacking with other foods containing caffeine; business purchase and resale online or as part of “health advice”).

- While it is understood that food manufacturers may need to source concentrated caffeine for technically justified reasons, it is unclear as to what controls will be place on the distribution of these highly concentrated caffeine products, should the suggested restrictions only apply to retail sale. These high caffeine products can be purchased online (from overseas), and it would seem even legitimate sites allow you to purchase these products if you are a business, without necessarily having the skills or knowledge to use the product in a safe and suitable way.

- Additionally, the risk management approach for caffeine does not align with the approach taken by the Therapeutic Goods Administration (TGA) where legislation requirements for warnings of POISON etc. Pure and highly concentrated forms of caffeine are not food. Pure and highly

concentrated caffeine should be regulated as a scheduled poison by TGA, perhaps in a similar way to how quinine is treated: https://www.tga.gov.au/book-page/32-quinine-and-its-salts

- The DOH is also concerned that 'new' caffeinated products will begin to enter the Australian food supply, some of which may be desirable to children. For example: Awake chocolates available in the US market/ online contain added caffeine, such that there is 110 mg of caffeine in a serving of one small bar of chocolate (around 100 mg / 45 g). These products appear to be marketed in a way to appeal to children, with cute owls stamped into the chocolate and colour packaging to match, not to mention flavours, like peanut butter. This company also produces caffeinated granola bars, with 50 mg of caffeine in a 40 g bar. Refer to https://awakechocolate.com/

Moving Forward: Considerations for FSANZ to address concerns about caffeine in the food supply

The DOH preferred approach is to support Option 3: prepare a proposal to amend and/or add to the approved variation.

As previously mentioned, the DOH alternative approach would be to amend Standard 1.1.1 – 10 (6) which states '*Unless expressly permitted by this Code, food for sale must not have as an ingredient or a component, any of the following*:
(j) raw apricot kernels;'
(k) *insert 'caffeine' here*

This would mean that caffeine, unless expressly permitted in the Code, could not be added to food. The permission to use caffeine as a food additive in kola-type beverages, and as an ingredient in FCBs, would still apply. Food containing caffeine naturally would still be permitted in line with Standard 1.1.1 -10 (7) which states '*Subsection (6) does not apply to a substance that is in a food for sale, or in an ingredient for sale, by natural occurrence'*.

Given it is clear that there is lots of uncertainty about the Code and how caffeine is intended to be regulated in the food supply, the DOH would like to following matters considered:

Food Labelling considerations for food containing caffeine
The DOH would welcome a requirement for the concentration of caffeine in food products to be declared on the food label, perhaps by way of addition of this information to the Nutrition Information Panel. This would enable consumers to make informed choice and manage any potential sensitivities to excessive caffeine consumption.

In addition, the requirement for FCB to carry a caffeine advisory statement on the label, should be extended to all products containing caffeine.

Definition of a Food Additive and Technological Function
There is a need to expedite a review of the food additives standard (Standard 1.3.1) and the definitions of technological purpose. The P1025 Code Revision does not limit the addition of food additives and substances to foods for technological purposes not listed in Schedule 14. This has resulted in an interpretation of permission, such that if caffeine is used as something other than a food additive, like a 'stimulant', then it would be permissible in a food, in an unspecified concentration.

Formulated Supplementary Sports Food
There seems to be subjectivity about caffeine and its use in formulated supplementary sports food, due to the Code being silent on the addition of caffeine in Standard 2.9.4. It is noted that Standard 2.9.4 is being reviewed as part of P1010, whereby consideration of an express permission for caffeine in this type of food, with appropriate limits would seemingly be captured. It may be that consideration of caffeine in these sports foods, could be considered independently of P1010, to expedite the process of providing a permission for caffeine in formulated supplementary sports

food, if that is the intention of FSANZ, and the reason for the amendment to the definition of food additive, to enable the use of caffeine as a 'stimulant' in these kinds of food products. Expediting consideration of the addition of caffeine to sports food would seem to be a more appropriate (proportionate) approach, than providing a general permission for caffeine in food for retail sale across the entire food supply (as is the case with the amendment to Standard 1.1.1 – 10 (5).

Botanical Sources of Caffeine

The DOH is aware that a number of jurisdictions have raise issues with botanical (natural) caffeine sources. Whilst the DOH appreciates this may be a little out of scope of the current work, natural sources of caffeine should be considered for the aspect of the whole of dietary exposure. In terms of botanical sources of caffeine, which potentially contribute to caffeine presence in a food where there is no express permission to add caffeine, limiting the total amount of caffeine permissible in food products containing botanicals like guarana or high caffeine coffee beans, may be worth consideration.

A maximum Limit (ML), in accordance with Standard 1.4.1 and Schedule 16, could be established for caffeine, in a similar manner to that which exists for quinine (Schedule 19 – 6 - Maximum level of natural toxicants). This way, where caffeine is permitted in the Code, it could only be added at a level less than or equal to the ML listed for caffeine in the final food products.