Urgent Proposal P1054 – Pure and highly concentrated caffeine products

Comments from the Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions.

Due date of submission – 14 November 2019

The Victorian Departments of Health and Human Services and Jobs, Precincts and Regions (the departments) welcome the opportunity to respond to this urgent proposal to amend Standard 1.1.1 of the Australia New Zealand Food Standards Code (the Code) to prohibit foods for retail sale that contain a concentration of 5% or more of caffeine.

The departments support regulation that restricts the sale of pure and highly concentrated caffeine products but **do not support this amendment to the Code as drafted** for the reasons that it:

- could pose health and safety risks from increasing the availability of caffeine in the food supply and high caffeine products.
- does not address the issue of access to concentrated caffeine products, and
- could have unintended consequences which include increasing caffeinated foods in the food supply and altering the operation of the Code more broadly.

Unintended consequences

1. Reduced regulatory clarity

It is the departments' view that it is the intention of the Code to prohibit the addition of caffeine to foods unless expressly permitted. The interpretation provided in P1054, that caffeine is permitted if a manufacturer decides to add it for a purpose other than as a food additive, creates a potential regulatory gap which needs to be addressed. The proposed maximum concentration limit does not address this gap and, by default, provides more weight to the interpretation that any food additive can be added to any food as long as it is for a different purpose and that, for caffeine, any food can contain up to 5% caffeine.

Evidence for the view that there is a prohibition on caffeine except for cola drinks, formulated caffeinated beverages and naturally occurring caffeine can be inferred from:

- The multiple enforcement decisions made through the Imported Food Inspection Scheme which has rejected foods at the border due to their caffeine content.
- The Food Regulation Standing Committee Caffeine Working Group's work and 2013 policy option paper on The Regulation of Caffeine in Foods. This described the historic and current permissions for caffeine being limited to cola drinks, formulated caffeinated beverages and naturally occurring caffeine.
- The existence of the Ministerial Policy Guideline for the Regulatory Management of Caffeine in the Food Supply, which discusses how the regulation of caffeine needs to consider intakes from all sources and the most vulnerable and caffeine sensitive populations.
- The existence of Standard 2.6.4 - Formulated Caffeinated Beverages, with associated advisory statements regarding the presence of caffeine and unsuitability for pregnant women and children. An interpretation where broad permissions for caffeine can be added to any food for reasons other than as a food additive suggests that Standard 2.6.4 would not be necessary. This interpretation would also mean food represented as a caffeinated beverage is limited to 0.032% caffeine and requires caffeine advisory statements, whereas other foods and beverages can contain any amount (and up to 5% caffeine under the current Proposal) with no advisory statements.

The perverse interpretation of a broad permission for caffeine when added as a stimulant has perhaps been prompted by the Code Revision work, intended to clarify the Code, which altered the wording around substances permissions. Where previously the Code specified that '*unless expressly permitted a food for sale must not have as an ingredient or component…a food additive*' the Code now specifies, *a substance that was 'used as a food additive'*. Prior to this, it may have been more clearly argued that caffeine is identified as a food additive in the Code and is only permitted in cola beverages and in Standard 2.6.4.

The issue with the interpretation and approach in Proposal P1054 is that it creates the above inconsistencies in the Code and undermines the historic operation of the Code which has been based on a positive list of permissions, rather than a negative list of prohibitions. This will reduce regulatory clarity across the Code and have implications for other substances. For example, if the proposed caffeine amendment proceeds, it could be argued that using the same interpretation, any food additive currently retricted to certain foods, could now be added to any food, and in any quantity, provided it is for an alternative function. This could then necessitate creating a negative list to place safety limits on these substances. Maintaining a negative list is extremely resource intensive and having concurrent negative and positive lists operating for the same substances is likely to add significant complexity to the Code, with associated regulatory uncertainty.

2. Increasing caffeine in the food supply

The Code acts as a platform for industry innovation by setting the regulatory boundaries. The previous enforcement action and wording of the Code, which more clearly restricted caffeine, are likely to have limited the market in caffeine products to date. Setting new, clear boundaries that only foods with levels above 5% caffeine are prohibited creates a new opportunity for product formulation up to this maximum. This proposed amendment could result in a significantly greater number of foods containing caffeine, at much higher levels than currently, with potential public health risks, particularly for children and those sensitive to caffeine.

3. Inconsistent regulation

The Therapeutic Goods Administration (TGA) has implemented an immediate maximum limit on undivided preparations (such as powders) of 4%, which is to decrease to 1% after March 2021. We are concerned that the proposed regulatory changes to TGA and the Code are not consistent. This may also prompt manufacturers to identify powders as a food, rather than a therapeutic, to enable them to add more caffeine.

Public health risks and access to concentrated caffeine products

FSANZ has proposed a prohibition on the retail sale of food above a concentration of 5% caffeine. It bases this on the concentration of existing powders containing caffeine (such as instant coffee powder containing 3.1-3.9% caffeine and pre-work-out supplement powders 0.6-4.04 % caffeine on average, noting if these are a Formulated Supplementary Sports Food, they are not permitted to contain caffeine). The Call for Submissions indicates up to 200mg is not considered to have safety concerns, the EFSA and the US FDA state 400mg/ day is safe for most adults, with death being noted at doses of 3000mg.

A broad concentration limit creates problems with the dose of caffeine readily available depending on the form of the food. For coffee, when brewed, the 4% caffeine of the coffee powder usually provides approximately 100mg of caffeine. Stronger brews and higher amounts of caffeine will be limited somewhat by taste. Adding a potentially tasteless powder containing 5% caffeine to a milkshake could quickly provide much higher levels of caffeine, with one tablespoon providing 825mg caffeine (assuming no other caffeine containing ingredients are present) and two tablespoons providing 1650mg caffeine, which is above the level known to cause ventricular

arrythmias and seizures. Liquid products potentially provide the opportunity for much higher doses. A 5% concentration equates to 5000mg per 100mL. In this form, a lethal dose of 3000mg could be obtained in 60mL, or two to three mouthfuls. The Department of Health and Human Services has been made aware of a product named a 'shot' but described as a concentrate, designed to be diluted. If a product like this applied the 5% maximum caffeine concentration, it could be mistaken as a 'shot' and a lethal dose easily consumed.

It is the departments' view that, apart from not addressing the regulatory gap identified, the proposed maximum concentration applied across all foods does not address the risk of highly concentrated caffeine products being available for retail sale.

Proposed solution

The departments agree that the potential lack of clarity about the regulatory status of caffeine permissions in foods necessitates action to prevent the sale of high caffeine products. The departments believe the appropriate solution consists of:

1. A temporary amendment to the Code under this Urgent Proposal that clarifies that the addition of caffeine to food is prohibited unless expressly permitted in the Code, while enabling the use of ingredients with naturally occurring caffeine (such as coffee and tea). The departments suggest an option could be to amend Standard 1.1.1-10 (6) as follows:

   (6) Unless expressly permitted by this Code, food for sale must not have as an ingredient or a component, any of the following:

   (k) caffeine

   (7) Subsection (6) does not apply to a substance that is in a food for sale, or in an ingredient of a food for sale, by natural occurrence.

2. A follow up amendment to Standard 1.1.1-10 (6) that prohibits, unless expressly permitted, an ingredient or a component that is used for a health effect/ physiological effect. Once gazetted, the specific prohibition on caffeine under this Standard should be removed to avoid the creation of a dual 'positive/negative list' of substances.

The changing food supply that results from industry innovation has created new reasons for adding substances to foods. We do not believe it was the intention of the Code that 'bioactive' substances or those with physiological or health effects should be permitted to be added to any food at any level, while food additives, nutritive substances, processing aids or novel foods require express permissions. This issue has been raised previously, such as when considering the addition of fructo-oligosaccharides (FOS) and galacto-oligosaccharides (GOS) to infant formula without express permission. The argument made at that time was that pre-market assessment was not required because these substances were not technically nutritive, food additives or processing aids, however there was discussion that these listed functions were meant to capture all reasons for adding substances. The Ministerial Policy Guideline developed following this incident clarified that all new substances require pre-market assessment for addition to infant formula. This example in infant formula illustrates the problem that the categories of functions currently available in the Code, and intended to capture the reasons for adding an ingredient, are no longer adequate.

The Proposal P1025 on Code Revision also discussed the issue in 2014 and indicated permissions would be further clarified under Proposal P1044 – nutritive substances and novel foods, which has recently been put on hold. Clarifying in the Code that biologically active substances should not be added to food unless expressly permitted must be progressed as a priority to address the potential regulatory gap identified by FSANZ in this proposal.