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

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

Due date of submission – 11 September 2020

The Victorian Departments of Health and Human Services and Jobs, Precincts and Regions (the departments) welcome the opportunity to respond to the Assessment of the Approved Variation.

Urgent Proposal P1054 introduced an amendment to 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 in solids and gels and 1% or more for liquids.

The departments agree that pure and highly caffeinated products should be prohibited for retail sale but continue to hold concerns about the implications of the recent limits introduced in Standard 1.1.1. For this reason, the departments support FSANZ's preferred option, Option 3: to prepare a proposal to amend and/or add to the approved variation. We note that this would mean that the current limits on caffeine introduced under P1054 would remain in place until amended by a further variation. We also note that a further variation would be developed by a new, separate proposal and that this new proposal must be prepared (but not completed) before 12 December 2020. This option needs to be expedited.

Rationale for amending the current variation

The departments have previously raised concerns (November 2019 Call for Submissions) with the introduction of maximum caffeine concentrations of 5% or more in solids and gels and 1% or more in liquids. While the limit for liquids was reduced from 5% to 1%, these concerns remain. In summary they are:

1. Protection of public health and safety

The departments' view is that the limits introduced do not protect public health and safety, nor do they prevent access to concentrated caffeine products. For instance, a 375 ml (can size) drink containing 0.9% caffeine would comply with the current limit. However, that drink would provide 3,375mg of caffeine which is greater than the dose found to be lethal (3000mg). Similarly, even if a manufacturer was to use half the permitted caffeine in liquids, this would provide 1875mg caffeine in a 375 ml drink, which is above the level FSANZ indicated to be associated with tachycardia, arrythmia, seizures and anxiety. In the departments' view these limits could result in products that are available on supermarket shelves and pose a risk to public health and safety, particularly to children.

2. Uncertainty about the regulatory status of caffeine and other food additives and associated enforcement difficulties

It is the departments' view that the intention of the Code has always been to prohibit the addition of caffeine to foods unless expressly permitted. Evidence for this was provided in our November 2019 comments. The current Call for Submissions similarly identifies that the then Australia and New Zealand Food Regulation Ministerial Council (4 April 2003) stated its view that addition of caffeine to other soft drinks was *not permitted.*

The Approved Variation for caffeine casts doubt on the operation of the Code with regard to what may lawfully be added to food. In particular, it has created regulatory uncertainty about the potential legitimacy of beverages containing less than 1% caffeine and solid foods and gels containing less than 5% caffeine.

In this Proposal P1054, FSANZ provides interpretation that, despite there being limitations in the Code on the addition of caffeine to cola drinks as a food additive and in caffeinated beverages, caffeine is

permitted broadly in foods if a manufacturer decides to add it for a different purpose that is not a food additive function.

This interpretation has arisen from an unintended consequence of drafting clarifications made to the Code in 2016. Previously, Standard 1.1.1 stated: '*unless expressly permitted a food for sale must not have as an ingredient or component…a food additive*'. Caffeine is considered a food additive for adding flavour to cola drinks, therefore it could not be added to other foods without permission. For example, a separate standard was created, 2.6.4, to permit caffeine to be added to formulated caffeinated beverages for 'mental stimulation'.

In 2016, Standard 1.1.1 was changed to: '*unless expressly permitted a food for sale must not have as an ingredient or component a substance that was '**used** as a food additive'.* The implication of this phrasing is an interpretation that express permission is only required if caffeine is used as a food additive, but not, for example, if used as a stimulant.

Failure to address this creates an undesirable regulatory situation where caffeine added for mental stimulation in a caffeinated beverage is limited to a maximum of 0.032% and requires caffeine advisory statements. However, when caffeine is added to beverages for physical stimulation or other reasons, it can now be permitted up to 1% with no volume limits or advisory statements.

This is at odds with the Australia and New Zealand Ministerial Forum on Food Regulation's historically conservative approach to caffeine permissions during the development of the standard for formulated caffeinated beverages, the ministerial policy guideline on the regulation of caffeine and, more recently, the Australian Government's request to strengthen regulations and consumer warnings on caffeine in food.

The caffeine limits also have implications for the types of enforcement action able to be taken for products that do not comply with existing caffeine permissions, for example under Standard 2.6.4.

This Approval Variation has unveiled broader implications of this interpretation for food additive permissions generally, effectively creating an disproportionate regulatory approach where the Code tightly regulates the addition of food additives to food where they perform a technological function (to protect public health and safety), but will allow the unregulated addition of those same substances when they are used for a physiological effect. This is at odds with the intent behind Standard 1.3.1, which was developed to ensure that the dietary exposure to food additives in the food supply does not present an unacceptable risk to public health and safety and that consumers are not exposed unnecessarily to high levels of food additives (from FSANZ's Proposal P1025).

Considerations for the new proposal

The departments are willing to assist FSANZ with the scope and background information for the new proposal to amend the approved variation and consider the broader permissions for caffeine in the food supply, taking into account sensitive populations.

The departments suggest the new proposal:

1. must resolve the ambiguity in permissions for the addition of caffeine to food, namely the prescriptive approach for two products (cola and formulated caffeinated beverages) but the simultaneous interpretation that caffeine can be added for other purposes to a broad range of foods up to 1% or 5%, depending on the form of the food. This includes clarifying the original intent that caffeine itself is prohibited to be added to food unless expressly permitted. The Code does not, or need to, prescribe limits for naturally occurring caffeine in food, for example teas, coffee and chocolate. Permissions for caffeine to be added to new products should be considered on a case by case basis and should consider the risk to the broader population, including sensitive groups.

2. must clearly describe when a caffeinated product is considered a food. Pure caffeine and highly concentrated caffeine products (that are effectively dilute caffeine and not derived by adding high amounts of caffeine to a food) should not be considered a food under the Code. These are therapeutic substances and are captured under the *Therapeutic Goods Act 1989*. The inclusion of 'pure caffeine' and 'highly concentrated caffeine' in the Code as foods creates unnecessary regulatory confusion and duplication across the food-medicine interface.
3. With resolution of caffeine permission ambiguities and clarification that pure caffeine is not a food, the proposal should reconsider the need for broad maximum limits for caffeine in food. Permissions for foods to contain added caffeine already include maximum limits, making these broad limits redundant. Consideration should be given to removal of the percentage limits on caffeine to address the regulatory ambiguities they create.

The departments also note that FSANZ had previously committed to addressing issues relating to food additives during Proposal P1025 Code Revision. This appears to have been put on hold. While reviewing food additives would be a separate piece of work, this caffeine proposal has revealed that an interpretation may be taken that other food additives could be added to food for purposes other than a technological function, without restriction. This presents a health and safety risk that should be addressed as a priority, particularly given the range of permitted flavouring substances (including those in the Flavour and Extract Manufacturers Association of the United States Generally Recognized as Safe list such as alkaloids and quinine). The departments suggest this issue needs to be addressed as a priority and could be included within the caffeine proposal. This could include consideration of removing the reference to 'used as a food additive' and replace it with 'the addition of any substance listed in Schedules 8, 15 or 16 is prohibited unless expressly permitted by this Code'.