

Proposal P1054

Pure and highly concentrated caffeine products

Call for Submissions

Submission

Summary

NSW welcomes the opportunity to comment on Proposal 1054 – Pure and highly concentrated caffeine products (P 1054). NSW supports the desired intent of P 1054 to prohibit the retail sale of pure and highly concentrated caffeine products as food.

The Call for Submissions (CFS) document requests stakeholder comment on whether the proposed 5% limit is likely to have any unintended consequences. Following review of the proposed drafting, NSW is concerned the proposed amendment to the Australia New Zealand Food Standards Code (the Code) might not resolve the current ambiguity that resides with its management of caffeine, and might be perceived by some stakeholders as a broad permission to add caffeine to all foods up to a limit of 5% (noting this is not the intent of Proposal 1054).

Regulatory status of foods with caffeine levels below the threshold

The clause in question for the proposed Code amendment (Standard 1.1.1-10(5)) in P 1054 begins with:

‘Unless expressly permitted by this Code, food for sale must not be any of the following...’

As noted by FSANZ in its recent Caffeine review¹ (pg 17) the regulatory status of caffeine is ambiguous.

‘There is a lack of clarity in situations where caffeine’s use in or addition to food does not fall with the Code’s definition of what constitutes ‘a food additive’, ‘a processing aid’, or a ‘nutritive substance’. There is no express requirement in the Code that prohibits caffeine’s use in or addition to food for other purposes’.

Currently there is no express permission in the Code for the general addition of caffeine to all foods, (*and the proposed variation does not seek to create one*) but the current Code does not provide a prohibition based threshold for caffeine that applies to all food for retail sale. The proposed drafting creates such a threshold which in the

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

absence of a general caffeine permission creates doubt as to the regulatory status of foods with caffeine levels below the threshold. Are these foods permitted to contain caffeine in the first place and if not why list a threshold? It would seem more practical to clarify, beyond reasonable doubt, that foods should not contain artificially added caffeine unless there is a specific permission in the Code.

NSW considers this clarity is of high importance as the FSANZ Caffeine report provides commentary that the function that may be served by caffeine when added to food is not expressly captured by existing Code prohibitions targeted at defined functions when intentionally added (i.e. food additive, processing aid, etc).

NSW is concerned that the absence of an express permission for caffeine in foods *where it is added as an ingredient in its own right*, coupled with a threshold based prohibition may be interpreted by some segments of the market as a general permission to add caffeine to any food at or below 5% concentration. This concern also extends to those products with existing permissions, provided the purpose served by caffeine when added to these foods is not that for which an existing lower threshold exists in the Code (i.e. used as a food additive – Cola drinks, or for the purpose of enhancing mental performance – caffeinated energy drinks).

Another possible example is a caffeinated energy drink that decides to increase its caffeine concentration above that permitted by Standard 2.6.4 (but below 5%) and decides to no longer present itself to the market as a 'caffeinated energy drink' for which the lower prescribed caffeine threshold in the Code would apply. It would be left to the enforcing jurisdiction to prove that an offence of Standard 1.1.1-10(5) has occurred (i.e. addition without express permission but below the prohibition threshold), when the manufacturer could claim that caffeine has been added '*for other purposes*' (i.e. not for the purpose of enhancing mental performance or as a food additive) and the product is no longer presented to the market as a '*caffeinated energy drink*'.

The explanatory statement provided in the CFS (pg 23) refutes the possible interpretation that a general permission for adding caffeine to food is created by the proposed drafting in P 1054 and states this is not legally possible (pg 23 of the CFS). This needs to withstand challenge and NSW assumes that FSANZ has sought legal advice.

NSW suggests the proposed variation to Standard 1.1.1-10 (5) in the CFS will not resolve the current ambiguity that resides with the addition of caffeine to food as the clause is silent on the use of caffeine when added to food.

Potential complication in using '*unsuitable food*' offences

As the proposed Code variation in P 1054 is silent on the function served by caffeine when added to food, NSW suggests that it may complicate the use of '*unsuitable food*' offences in the NSW *Food Act 2003* as synthetically produced caffeine could be argued to be no longer '*a biological or chemical agent, or other matter or substance, that is foreign to the nature of the food*' as the proposed Code variation in P 1054 may be argued to have the effect of creating a permission to add caffeine to food so long as it is below the 5% threshold.

Given arguments above concerning the uncertainty of permission for adding caffeine to food when it is used for *'for other purposes'* there is a risk the proposed Code variation in P 1054 would complicate use of *'unsuitable food'* provisions by jurisdictions to remove product from the market if it is suspected of causing harm to public health and safety. Jurisdictions may be required to default to the higher bar of *'unsafe food'* before potentially hazardous product could be removed from the market, even if was associated with human health impacts among sensitive sections of the population (e.g. young children, teenagers, pregnant women).

Disparity of the proposed threshold with TGA

NSW is also concerned about the disparity of concentration of the proposed Code amendment in P 1054 with the intended listing of substances with greater than 4% concentration of caffeine as Schedule 6 poisons under Therapeutic Goods Administration legislation. It would seem illogical to require a substance with a 4% caffeine concentration to require labelling as a 'poison' but another substance with 4.8% caffeine could present itself as food.

Alternative amendment

NSW proposes an alternate Code amendment below (in red) to Standard 1.1.1-10 (6) as a substitute to that provided in the Call for Submissions. NSW suggests that placing the amendment in this section of the Code is more aligned with the purpose of P 1054 – to prohibit the use of pure and highly concentrated caffeine in food for retail sale as it extends to ingredients and components as well as to matters for which specific permissions are required (e.g. processing aids, food additives).

1.1.1—10 Requirements relating to food for sale

- (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 including any derivatives or plant concentrates of caffeine unless sold for manufacturing purposes only**
- (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.

Location in Standard 1.1.1-10 (6) provides for application of a specific permission for use in caffeine, irrespective of purpose of addition. There may be also merit in listing caffeine under both Standard 1.1.1-10(5) and 1.1.1-10(6) as the prohibition will apply to use as an ingredient or component in food for sale (as provided above) as well as to final foods for retail sale (possibly listed as caffeine for retail sale under Standard 1.1.1-10(5)) similar to how raw apricot kernels are listed). The underpinning logic is caffeine in and of itself should not be a food for retail sale as it is a drug, nor should it be permitted for addition as an ingredient or component in a food for sale without an express permission in the Code - unless it is sold for manufacturing purposes to make food for retail sale that has express permissions in the Code to contain caffeine. This would target addition of synthetically produced caffeine to all food and not require a threshold. Naturally occurring caffeine in existing foods (e.g. coffee, tea, guarana) would continue to be exempted from these prohibitions under Standard 1.1.1-10(7). However when a product is artificially concentrated to synthetically

elevate its caffeine limits (e.g. guarana extract) – the protection of ‘naturally occurring’ should be lost as this is now manufacture akin to preparation of synthetic caffeine.

Such a proposal may require listing of caffeinated energy beverages as a defined class of food in Standard 1.1.1-10(6) for which caffeine is permitted so there is no internal conflict in the reading of the Code as a single instrument (Standard 1.1.1-2(1)).

Use of a lower threshold

Notwithstanding the above suggestions concerning location of Code amendments for this Proposal, NSW has sought advice on the merits of the proposed 5% threshold and suggests that it should be lower. The CFS suggests that 3000mg/100g may present a lethal dose to some members of the community (pg 10 of CFS). NSW is concerned that 5% (5000mg/100g) increases the potential for new highly caffeinated products to enter the market. There is some literature suggesting that ingestion of 5000mg of caffeine as a single dose is associated with life threatening consequences such as malignant cardiac arrhythmias².

The website of Sports Dietitians Australia suggests a lower threshold of 1-3 mg of caffeine per kg of body weight (up to 210mg for a 70kg athlete) is a more appropriate upper limit³.

The scientific opinion on the safety of caffeine developed by the European Food Safety Authority (EFSA) in 2015⁴ suggests the maximum dose of caffeine derived from a single serve should be no more than 200mg.

The same EFSA advice further advises that 400mg of caffeine may be consumed from all dietary sources per day without giving rise to safety concerns.

A review of websites of European regulators and Health Canada concurs with this advice:

- Food Standards Agency United Kingdom⁵
- Food Safety Agency of Ireland⁶
- French Agency for Food, Environmental and Occupational Health and Safety⁷
- Health Canada⁸

NSW queries why FSANZ has elected to suggest that a 5% threshold is appropriate, noting that it could deliver 825mg of caffeine in a single teaspoon. FSANZ suggests

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6011436/>

³ <https://www.sportsdietitians.com.au/factsheets/supplements/caffeine/>

⁴ <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.4102>

⁵ <https://www.food.gov.uk/safety-hygiene/food-additives>

⁶ [FSAI caffeine.pdf](#)

⁷ <https://www.anses.fr/en/content/caffeine-and-health>

⁸ [IFT report on health Canada caffeine safe levels May 2017](#)

this dose would not result in acute toxicity but is associated with unpleasant side effects such as anxiety, particularly susceptible sub-populations as pregnant women and children (pg 10-11 of the CFS). This is considered sufficient concern to propose a lower total concentration so these effects are avoided.

A factsheet of caffeine concentration of common products on the Australian market published by the Alcohol and Drug Foundation⁹ cites caffeine concentrations in Coca-Cola of 9.7mg/100ml¹⁰, Red Bull of 32.0mg/100ml and coffee espresso style at 194mg/100ml. This same factsheet cites in Australia between 2004 – 2010 there were 297 calls to the NSW poisons information line concerning toxicity associated with consumption of caffeinated energy drinks. Commonly reported symptoms were palpitations/ tachycardia, tremors, shaking, agitation and restlessness. These figures suggest the notion of a threshold permitting 825mg of caffeine in a heaped teaspoon is far too high (pg 10 of CFS).

NSW further queries how the 5% threshold would be applied to foods currently in the market and to future foods. If caffeine is not permitted to be present in the first place, how is the 5% threshold to be applied to food? Would it be on the food for sale as presented to the market (i.e. as sold) or 'as prepared'? Clarification on this matter would be appreciated.

'Safe Harbour' provision

A further matter for clarity is the 12 month 'safe harbour' provision provided by Standard 1.1.1-9. Would this apply to all caffeinated products presenting as food for retail sale currently in the market at the date the proposed variation is gazetted?

ENDS

The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.

⁹ <https://cdn.adf.org.au/media/documents/Caffeine-drug-facts.pdf>

¹⁰ <https://www.coca-colacompany.com/stories/0000014b-079f-da6b-ad6f-6fdf6be40000>