SA HEALTH SUBMISSION ON -

P1054 – Pure and highly concentrated caffeine products

November 2019

SA Health welcomes the opportunity to provide comment on P1054 – Pure and highly concentrated caffeine products.

SA Health is of the view that the Proposal as drafted does not provide any further regulatory certainty for enforcement purposes.

1. The Food Acts of the States and territories will prohibit the sale of a food that is not safe and suitable.
2. The Therapeutic drugs regulations and/or poisons schedules should be used to restrict or provide warning about caffeine at retail sale if risk assessment determines that it needs to be controlled. This is appropriate for a substance sold at retail that may be a poison. The TGA has implemented an immediate maximum limit on undivided preparations (such as powders) of 4%, which is to drop 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.
3. Caffeine has not been approved as a novel food in the Food standards Code.
4. Any change to the Code regarding caffeine would also need to comply with the Caffeine Policy guidelines.
5. Caffeine is classified in the Food Standards Code as a food additive as listed in Schedule 15. Caffeine does not have an ADI and so is considered safe and is limited by GMP. The use of caffeine is expressly prohibited other than where expressly permitted.
6. There is currently no express permission in the Code to use caffeine other than in Cola drinks to provide the function of flavouring and in formulated caffeinated beverages as an ingredient.
7. One of the foundation principles in the Food StandardsCode is - addition of a food additive to food is expressly prohibited other than where expressly permitted in the schedules to the standard and is required to be used consistent with good manufacturing practice (GMP).
8. Food additives are placed in a “positive list” of permitted substances to be added to food which regulates there safe use. So if a substance is not performing a technological function in the food it is not permitted to be used unless expressly permitted. The Code effectively bans the use of the food additive unless there is a permission found elsewhere in the Code.
9. The proposal would establish a “negative list” of ingredients that are not permitted in food. This list would introduce a new principle in the way the Food Standards Code operates. The consequence of the Proposal would be that any food additive when not used to perform a technological function could be added at any level in a food. A manufacturer could decide that it was adding a food additive for any other purpose that a food additive as described as functioning, without limitation. The food additive standard would fail to operate as it was intended to work. A difficulty with a negative list is that many substances are permitted to be used until added on the list. The Code has operated by giving permissions for substances to be added to food when listed. This proposal creates a regulatory gap when used alongside a positive list of substances.
10. For example: Hydrochloric acid and phosphoric acid are food additives. If sold not for the purpose of a food additive and sold as food, then they are not currently prohibited expressly from being used for a non-food additive purpose. It would need to be added to the negative list of the Proposal next to caffeine if considered unsafe when consumed in pure form. So a negative list will exist alongside the positive list, which will add to confusion in interpretation of permissions.
11. Where caffeine is used for other purposes other than a food additive, etc, there will be another express permission required to be listed in the Code (Standard 1.1.1)

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

*(a) a substance that was *used as a food additive;*

*(b) a substance that was *used as a nutritive substance;*

*(f) if the food is for retail sale—a *novel food;*

*(g) a *food produced using gene technology;*

(h) a food that has been irradiated;

(i) kava or any substance derived from kava;

(j) raw apricot kernels.

***Note 1** Relevant permissions for subsections (5) and (6) are contained in various standards. See in particular:*

- *food additives—Standard 1.3.1;*
- *nutritive substances—Standard 1.3.2, Standard 2.6.2, Standard 2.9.1, Standard 2.9.2, Standard 2.9.3, Standard 2.9.4, and Standard 2.9.5;*
- *processing aids—Standard 1.3.3;*
- *agvet chemical residues—Standard 1.4.2;*
- *prohibited plants and fungi—Standard 1.4.4;*
- *novel foods—Standard 1.5.1;*
- *food produced using gene technology—Standard 1.5.2;*
- *irradiated food—Standard 1.5.3;*
- *kava—Standard 2.6.3.*

***Note 2** There is an overlap between some of these categories. For example, some substances may be used as a food additive or as a nutritive substance. For such substances, there will be different provisions permitting use of the substance for different purposes.*

***Note 3** In some cases, a provision refers to the total amount of a substance added to a food. In these cases, the total amount applies irrespective of whether the substance was used as a food additive, used as a processing aid or used as a nutritive substance.*

***Note 4** Relevant permissions for raw apricot kernels are contained in Standard 1.4.4.*

(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.

12. In formulated caffeinated beverages caffeine is used for another purpose other than as an additive and an express permission is provided in Standard 2.6.4.

2.6.4—3 Composition—formulated caffeinated beverages

A formulated caffeinated beverage:

(a) must contain no less than 145 mg/L and no more than 320 mg/L of caffeine in total, from any source; and

(b) may contain a listed substance.

13. The Code does not prescribe limits for naturally occurring caffeine in food – for example teas, coffee and guarana. (The Report from the Expert working group on the safety aspects of dietary caffeine (ANZFA, 2000)).
14. The proposed amendment to the Code will provide a new, express permission for any food to contain caffeine up to 5%. We disagree with FSANZ's stated view that the amendment will not constitute a permission to add caffeine to all foods, which it states will still be limited by Standard 1.1.1-10. FSANZ explained the reason for needing the proposed amendment is that caffeine does not always function as a food additive, and therefore addition is not always limited by 1.1.1-10. As long as a manufacturer contends the purpose of adding caffeine is not as a food additive (eg as a stimulant), it will be able to add it to any food up to 5%. The urgent proposal is meant to deal with one specific issue – prohibiting pure or highly concentrated caffeinated food. It is not appropriate to introduce new broad permissions through this process.
15. Do not support the use of a percentage limit to ban caffeine. A percentage limit of caffeine in food is difficult to enforce. An MPL means the maximum permitted level, measured (unless otherwise indicated) in mg/kg is more appropriate and consistent with the Code.
16. If there is concern that caffeine is being sold at retail as a single ingredient, then the food additives standard should be amended to restrict the retail sale of caffeine by adding a condition. Alternatively, caffeine as a food could be given permission as a novel food with limits on its use. Both these suggested ways of amending the Code would provide an express permission for caffeine with a limit or condition applied.