SA HEALTH SUBMISSION ON -

P1054 – Pure and highly concentrated caffeine products

11 September 2020

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

SA Health suggests option 2 together with option 3 should be considered.

Option 2

- prepare a proposal to repeal the approved variation; meaning the measure is no longer warranted.

and

Option 3

- prepare a new proposal to broadly regulate caffeine in food consistent with the objectives of the FSANZ Act, the Caffeine policy guidelines and the operating principles of the Food Standards Code (particularly the food additive standard).

This consists of the following:

- do not reaffirm the amendment to standard 1.1.1–10(5), noting that this would not remove the approved variation until a separate proposal was prepared by FSANZ and the approved variation was repealed
- following repeal, the Code would continue to operate as it did before the P1054 urgent measure was put in place.
- Prepare a new proposal to broadly regulate caffeine in food.

Repeal is supported because of the following:

1. The prescribed maximum limits for caffeine introduced by P1054 are in our view an interim measure to protect public health and safety. They can be repealed if the Code is amended to prohibit the addition of caffeine to foods unless expressly permitted, and maximum compositional limits set where permitted (e.g. for cola drinks and formulated caffeinated beverages). Furthermore, the limits introduced by the Therapeutic Goods Administration should address the risks from pure and highly concentrated caffeine products that are not foods.

2. The Food Acts of the States and territories will continue to prohibit the sale of a food that is not safe and suitable - including caffeine use as a food.

3. Pure and highly concentrated caffeine products should not be considered food; the TGA is best placed to regulate these products. The Therapeutic drugs regulations and/or poisons schedules recent changes implemented

since the commencement of Proposal P1054 can now be used to restrict the use of caffeine in pure and highly concentrated products. 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. Hence the repeal would remove the amendments of P1054 that are no longer required. On 1 June 2020, the Poisons Standard (No.2) June 2020 amended schedules 4 and 6 of the Poisons Standard, to strengthen the regulation of caffeine regarding pure or highly concentrated caffeine powder, due to the risk of poisoning.

4. The Poisons Standard exempts nearly all food. Advice to FSANZ is that exemptions in the Poisons Standard mean that any restrictions imposed as a result of that listing can only apply to the following foods:
    a. Food additives that contain or comprise the listed preparation but only prior to those food additives' incorporation into food.
    b. Any food that is used as a means of administering the listed preparation for 'therapeutic use' (as defined by the TG Act).

5. We are concerned that the regulatory changes to TGA and the Code are not consistent. This may prompt manufacturers to identify powders as a food, rather than a therapeutic, to enable them to add more caffeine. The amendment of Proposal P1054 is no longer needed because the TGA therapeutic and poisons regulations are in place.

6. There is no evidence provided that the amendment of Proposal P1054 is effectively regulating the use of caffeine as a food to prevent the caffeine poisoning case that prompted the development of the regulation in the first place.

7. The amendment to the Code provided a new, express permission for any food to contain caffeine up to 5% depending on food form. 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 the 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 instead), it will be able to add it to any food up to 5%. So if a manufacture of a cola drink uses caffeine as a flavour up to the permitted level of a food additive, it may also add more caffeine up the percentage level introduced by P1054 providing it is being added as a stimulant and not used as a food additive. Similarly, a lemonade that does not have a permission for caffeine as a flavouring can add up to 1% caffeine provided it is added as a stimulant and not a food additive.

8. The Code currently provides permission using the amendment introduced by Proposal P1054 to add caffeine as a stimulant to a broad range of solid foods up to 5% caffeine. There are already products using this regulation, such as "Awake caffeinated milk chocolate" offered for sale. Ingredients: Milk Chocolate (sugar, Cocoa Butter, Chocolate Liquor, Whole Milk Powder, Soy

Lecithin (added As an Emulsifier), Natural Vanilla Extract), **Caffeine**, Soybean Oil. This is added caffeine not caffeine as a natural component of chocolate.

9. The amendment has instead provided a clear permission to add caffeine to all foods since it is not effectively regulated as a stimulant and makes the food additive standard permissions ineffective. This may have the effect a greater consumption of caffeine in the total diet and may have health and safety implications for the public.

10. 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.

A new proposal being raised by FSANZ to regulate caffeine more broadly in food is supported and should consider -

11. 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 that makes it clear that caffeine is expressly prohibited other than where expressly permitted.

12. 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.

13. Caffeine has not been approved as a novel food in the Food standards Code.

14. Any change to the Code regarding caffeine would also need to comply with the Caffeine Policy guidelines.

15. Caffeine is classified in the Food Standards Code as a food additive as listed in Schedule 15 with the purpose of flavouring. 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.

16. 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.

17. One of the foundation principles in the Food Standards Code 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).

18. 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.

19. The proposal P 1054 established a “negative list” of ingredients that are not permitted in food. This list introduced a new principle in the way the Food Standards Code operates. The consequence of the Proposal is that any food additive when not used to perform a technological function can be added at any level in any 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 fails 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.

20. 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.

21. 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.

22. 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)).

23. 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.