13th February 2023

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To whom it may concern,
Submission Re – P1056: Caffeine review

1. **Do you consider there are risks to consumers from caffeine in the current market environment, under the current regulations? Please provide any evidence or relevant examples in detail to assist FSANZ in its assessment.**

For an informed consumer, the risk is relatively low. However, for consumers who consume (individual) high caffeine supplements or stack several caffeine products (Paisley 2015), there may be a moderate risk, as confirmed by individual case studies (Harris et al. 2017, Bridwell et al 2020) and case summaries (de Jonge et al 2023) reported in the literature. A recent review of pre-workout supplements commercially available in Australia confirmed a caffeine content ranging from 91-387 mg per serve (Desbrow et al 2018). However, only 6 of the 15 products reviewed included details on the caffeine content, with the investigation also confirming meaningful differences in the actual caffeine content relative to that specified on the label. It is unclear if current regulations would remove such risk from these high caffeine products. Clear articulation of the caffeine dose in the product and a maximum daily caffeine dose would assist a consumer to make informed decisions about their use of caffeine, particularly from products such as pre-workout supplements.

2. **Do you have any thoughts on FSANZ's preferred option that if caffeine is prohibited to be added to all foods apart from cola-type drinks, FCBs and FSSF, that a pre-market assessment is then required to add caffeine to any other food? If not, are there other approaches that would better address the problem?**

It is difficult to find a currently justifiable purpose for the addition of caffeine to any food, other than cola drinks, FCBs and FSSF. On this basis, a pre-market assessment is potentially not warranted. However, the availability of the pre-market assessment option provides an approach that is likely to be more amenable to industry and may accommodate future evolution of the food industry or science-based uses of caffeine, affording greater longevity to the regulatory measure.

3. **Do you foresee any compliance or enforcement issues with the preferred approach of expressly permitting total caffeine in FSSF at a maximum one-day quantity of 200 mg, whilst expressly prohibiting the addition of caffeine to all foods apart from cola-type drinks and FCBs?**

Yes, relatively recent research on the caffeine content of pre-workout supplements confirms there are several issues, including a failure to report caffeine content and disparity between reported caffeine content and actual content (Desbrow et al 2018). Furthermore, 7 of the 15 supplements assayed had a caffeine content per serve in excess of 200 mg. As such, with implementation of the preferred approach, half the market products would require reformulation. This would clearly require compliance assessments, including random assessment of true caffeine content via chemical assays. The prohibition of caffeine as an additive to all other foods except cola-type drinks and FCBs is less likely to be an issue, although vigilance may also be needed.

4. **Are there other supporting measures that FSANZ should consider, whether regulatory or non-regulatory?**

The proposed labelling of FSSF containing caffeine is appropriate and strongly supported. Will the 200 mg one-day quantify limit for FSSFs include only caffeine, or will it also include 'related compounds', including other methylxanthines? For example, how would the caffeine and other methylxanthines present in guarana be considered in FSSFs?

5. **Can you share any further knowledge of current research about?**
   a. **the health effects of caffeine,**
   b. **global developments in caffeinated food products, or regulatory approaches being taken in comparable markets?**

We are aware that the available research notes the absence of health effects and some health benefits associated with caffeine consumption in the general community. However, this may also reflect the properties of the historical source of the caffeine (e.g., coffee, tea) and their antioxidant/phytochemical ingredients. Given there has been a shift in population use of caffeine towards energy drinks, frappe and syrup added coffees etc, should new surveys and studies be a priority to assess the indirect health issues associated with this change in consumption patterns?

6. In the medium term, does your company have any plans to expand the number of SKUs that contain caffeine? What would be the nature of those SKUs?

7. Do the current regulations around caffeine, in particular where cola-type drinks and FCBs are concerned, allow for your future product development needs? If not, please explain why not and what regulation you think would be more suitable?

8. Beyond the mandated labelling imposed by the Code, is there any current or planned industry led mitigation measures to reduce consumers' exposure to caffeine?

9. Will your company be prepared to help develop non-regulatory measures to monitor and manage the number of food products that contain caffeine?

10. For product developers considering the addition of plant or other extracts containing caffeine, do you consider these would meet the definition of a novel food and therefore require a pre-market safety assessment?

11. How many stock keeping units (SKUs) will be affected by the proposed changes, for either FSSF or other foods, or both?

12. If your business has any SKUs affected, then:
    a. what is the nature of those products, and
    b. what action will you take in response to the regulation (for example, withdraw the product, reformulate the product, update labels to meet new requirements, etc)?

13. What will the cost of the above action(s) be? Be as specific as possible, and please separate the cost by type, for example, reformulation, re-labelling, write-off of existing stock etc.

14. For any of your existing SKUs likely to be affected by the regulatory option, typically how long do those SKUs take to be sold?

15. **To what extent do you agree that there are relatively few general foods (i.e., not FSSF) that contain added caffeine (i.e., foods that will be impacted by the proposal) and are currently sold in Australia and New Zealand?**

We are unaware of any general foods that contain added caffeine. However, it may be worthwhile exploring other related products, including those promoted for weight loss and nootropic products. For example, Choice has done a summary of nootropics but only based around label review…

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It would be interesting to test the preferred regulatory option against other popular products such as coffee flavoured milks. Research from 2012 confirmed a small number of products (4 of 20) had caffeine content in excess of 150mg per serve (Desbrow et al 2012). Since that time, there has been a trend for double and triple 'shot' products, albeit it where the caffeine is derived exclusively from the coffee, which appears in the ingredient list.

16. **Are there any unintended consequences of the proposal?**

No.

17. **How effective do you believe each of the proposed options would be in achieving the objectives of this proposal and why? In particular, consider risks of over-consumption of caffeine for sensitive sub-populations.**

Option 1: Difficult to assess compliance, and unlikely to impact availability of higher risk, high caffeine products such as pre-workout supplements. Limited ability in reducing risk of over-consumption of caffeine.
Option 2: While consumer education is admirable and should be encouraged, it is unlikely to impact caffeine practices. Limited ability in reducing risk of over-consumption of caffeine.
Option 3: Enforcing one-day quantity limits of total caffeine up to 200 mg will require higher caffeine products to be reformulated. Combined with appropriate education (including the mandating of caffeine content to be specified for all FSSFs with added caffeine, this is most likely to reduce rick of over-consumption of caffeine.

18. **Do you have any other comments on the benefits or costs of the proposed options?**

No.

References

Bridwell et al. Chest pain from supplement use in an active-duty soldier: A case study. Military Medicine. 185:e1857-e1859, 2020.

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Harris et al. Hemorrhagic stroke in a young healthy male following use of pre-workout supplement animal rage XL. Military Medicine. 182:e2030-e2033, 2017.

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Paisley. Nutritional and sports supplement use among deployed US army soldiers in a remote, austere combat outpost in Eastern Afghanistan. Military Medicine 180:391-401, 2015.