

Comments from the Victorian Department of Health and the Victorian Department of Energy, Environment and Climate Action.

Due date of submission – 13 February 2023

The Victorian Departments of Health and Energy, Environment and Climate Action (the departments) welcome the opportunity to provide comments on Proposal P1056 Caffeine Review.

The departments understand Proposal P1056 has been raised following the completion of Urgent Proposal P1054 for the purpose of assessing whether additional measures are required to protect public health and safety related to caffeine in the food supply. Based on the safety, dietary intake and social science assessments, FSANZ's preferred approach is a hybrid mix of regulatory and non-regulatory measures (Option 3). The proposed measures are:

- an express permission to add caffeine to Formulated Supplementary Sports Foods (FSSFs), with total caffeine up to 200mg in a one-day quantity;
- an express prohibition on the addition of caffeine to foods for retail sale other than those that have a specific permission (i.e., cola-type drinks and formulated caffeinated beverages (FCBs)); and,
- educational materials on the risks of pure and concentrated caffeine products, and hazards of caffeine in some population groups.

The departments agree in principle that Option 3 is the most appropriate response. As outlined in the Call for Submissions, caffeine poses several potential acute and prolonged health and safety risks to consumers, with a greater magnitude of risk among selected sub-populations. In the context of recent market trends that have increased the availability and promotion of caffeine-containing beverages, careful management of caffeine in the food supply is necessary.

While the departments support the progression Proposal P1056, we have identified several matters that should be further considered prior to drafting amendments. These are detailed below.

Pure and highly concentrated caffeine products

The Call for Submissions states that the proposed express prohibition on the addition of caffeine to foods for retail sale unless expressly permitted will remove the requirement for the P1054 variation and as such, will be removed. However, unlike FCBs and cola drinks, FSANZ has not proposed composition limits on caffeine in FSSFs, other than the maximum one-day quantity, which the departments understand directs certain labelling requirements but does not limit total quantity. Thus, the proposed removal of the P1054 variation could again permit pure and highly concentrated caffeinated FSSFs. For example, a highly concentrated powdered caffeine product for sports purposes could be sold containing multiple one-day quantities within the container.

This would not be consistent with the original intent of the caffeine review, which was to address the unacceptably high risk posed by pure and highly concentrated caffeinated products. We understand recent changes to the *Therapeutic Goods Act 1989* would mean that such products would be regulated as therapeutic goods. However, as this regulatory remit is outside the food regulation system, the departments suggest an explicit caffeine

limit for FSSFs in the Code should be considered to provide clarity and assurance that pure and highly concentrated caffeinated products are high risk products that should not be sold as foods. The compositional limit could be implemented through Standard 2.9.4 or Schedule 29 and would need to specify maximum permitted caffeine levels in powdered and liquid products based on safety data and expected serving size. For example, as outlined in the departments previous comments to Proposal P1054, a 1% limit in liquid products would not be appropriate given the maximum limit would pose critical safety risks in a standard 375ml serving size.

Risk to adolescences

The departments note the *Ministerial Policy Guideline on the Regulatory Management of Caffeine in the Food Supply* recognises the vulnerability of adolescents and the need for risk-appropriate regulation of caffeine. The departments are of the view that the assessment of the risk to adolescents requires further consideration to ensure alignment with the policy guideline. The specific areas of consideration are detailed below.

FSANZ's safety assessment identified caffeine clearance in adolescents is at least equivalent to that of adults and on that basis, suggests the recommended level for adults (i.e. 5.7 mg/kg bw/day) is also applicable to adolescents. While the 2015 Scientific Opinion on the safety of caffeine by the EFSA Panel on Dietetic Products, Nutrition and Allergies similarly noted the comparable caffeine clearance among adults and adolescents, the panel instead concluded 3mg/kg bw/day to be an appropriate level of no safety concern among children and adolescents due to limited data on the long-term effects of habitual caffeine consumption. This is also consistent with more recent assessments by international health authorities, which concluded between 2.5 – 3mg/kg bw/day is the recommended maximum/level of no safety concern for adolescents^{1,2,3}. The departments suggest the recommended maximum level of caffeine for adolescents should be reconsidered to align with international consensus and the intent of the Policy Guideline.

The departments also recommend further consideration is given to single dose safety limits in adolescents and how these correspond to current and proposed risk mitigation strategies. The departments are concerned that under the proposed approach some adolescents may not be adequately protected from acute caffeine-related safety risks. For example, a 16 year old on the 50th percentile (approximately 55kg for girls and 60kg for boys⁴) consuming the proposed one-day quantity of a FSSFs of 200mg (which is often the same as the quantity intended to be consumed in a single serving) would exceed the acute safety level of 3mg/kg bw (165mg for a 55kg female and 180mg for a 60kg male). While FSANZ's safety assessment acknowledges infants and children are at increased risk of acute toxicity, the departments believe this is also applicable to adolescent populations

¹ <https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/caffeine-foods.html>

² Norwegian Scientific Committee for Food and Environment. 2019. Risk assessment of energy drinks and caffeine.

https://vkm.no/download/18.416a9e91169d82a695d8bc8e/1554705398914/Energy%20drinks%20and%20caffeine_final_02.04.2019_revised.pdf

³ : National Institute for Public Health and the Environment. 2020. Risk assessment of caffeine in food supplements. <https://www.rivm.nl/bibliotheek/rapporten/2020-0022.pdf>

⁴ https://www.cdc.gov/growthcharts/html_charts/wtage.htm

(although to a lesser extent) as demonstrated by the previous example. Compositional limits and labelling requirements as well as non-regulatory measures (e.g., education) should be reconsidered given these risks.

While the departments note FSANZ's dietary intake assessment found that no or few children or adolescents regularly exceeded recommended maximum safe levels, the departments are concerned the assessment does not reflect the true extent of caffeine exposure due to the significant increase in the availability of caffeinated beverages since the 2011-12 NNPAS that informed the dietary intake assessment. This includes the recent introduction of caffeine into traditionally non-caffeinated products, such as the launch of Sprite Lemon Plus, and the increase in the availability and promotion of caffeinated sports supplements. While the departments are not aware of any Australian surveys of caffeinated sports supplement use, recent evidence suggests sports supplements more generally are commonly used by Australian teenagers. One Australian study reported almost half the surveyed boys aged 14 – 16 years currently use a sports protein powder⁵. While this study did not specifically measure caffeinated supplements, users of sports foods are commonly known to 'stack' (co-consume) multiple sports foods. Additionally, studies in other high-income countries have reported concurrent use of protein and caffeine-containing 'pre-workout' supplements is commonplace⁶.

Education materials

The departments support the development of education materials as a complementary strategy to manage public safety risks related to caffeine consumption. We note the Call for Submissions specifically identifies parents and caregivers of infants and pre-schoolers as a priority target population for education materials. The departments strongly encourage the inclusion of other target populations, specifically adolescents and parents and caregivers of adolescents due to the risks outlined earlier and evidence that understanding of caffeine presence and content is low^{7,8}.

Questions posed to submitters:

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.

The departments previously outlined a number of concerning risks introduced under Urgent Proposal P1054 in our comments to the Call for Submission in November 2019 and September 2020. These included the potential for increasing the number of caffeinated

⁵ Yager, Z. and McLean, S., 2020. Muscle building supplement use in Australian adolescent boys: relationships with body image, weight lifting, and sports engagement. *BMC pediatrics*, 20, pp.1-9.

⁶ Shoshan, T. and Post, E., 2021. Prevalence of Protein and Pre-Workout Supplement Use among High School Football Players and Potential Product Contamination. *Global Pediatric Health*, 8, p.2333794X211031202.

⁷ Costa, B.M., Hayley, A. and Miller, P., 2016. Adolescent energy drink consumption: An Australian perspective. *Appetite*, 105, pp.638-642.

⁸ Francis, J., Martin, K., Costa, B., Christian, H., Kaur, S., Harray, A., Barblett, A., Oddy, W.H., Ambrosini, G., Allen, K. and Trapp, G., 2017. Informing intervention strategies to reduce energy drink consumption in young people: findings from qualitative research. *Journal of nutrition education and behavior*, 49(9), pp.724-733.

foods in the food supply and permitting caffeine at potentially hazardous levels. These risks remain current while the P1054 variation in its current form remains in place.

The departments also consider caffeine-containing sports supplements have the potential to pose both acute and sustained health and safety risks under the current regulatory framework that does not recognise or place any controls on these products. This is evidenced by the numerous high caffeine products available promoted as delivering as much as 400 – 500mg of caffeine⁹ per suggested serve. While we recognise the proposed caffeine limit in a one-day quantity goes some of the way to minimise current risks, effectiveness of this control requires FSSF consumers to be aware of, and adhere to, recommended product quantities. The departments are aware that some FSSF producers and retailers currently promote 'double serving' to provide very high caffeine levels (see Figure 1 as an example). Such practices undermine the purpose of a recommended one-day quantity and promotes unsafe consumption behaviours. FSANZ should ensure drafting prevents such unsafe promotions.



DISORDER

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Mega Pre Workout for Intense Focus, Pump & Energy

- 500mg Caffeine per Double Serving
- Extreme Energy & Sharp Focus
- More Strength & Pumps
- Delicious Flavours

Figure 1. Example of a 'double serving' promotion on an Australia supplement website
Source: <https://www.mrsupplement.com.au/faction-labs-disorder>

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?

The departments support FSANZ's preferred approach and believe explicit prohibitions are necessary to provide regulatory clarity. 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 to Urgent Proposal P1054.

⁹ <https://www.mrsupplement.com.au/strongest-pre-workout>

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?

The departments do not foresee any compliance and enforcement issues with the proposed approach. However, as raised above, we are concerned that a maximum one-day quantity without any compositional limit for FSSFs will not prohibit pure and highly concentrated caffeine supplements being sold as sports foods.

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

The departments have no other supporting measures to suggest.

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**
- c. regulatory approaches being taken in comparable markets?**

The department have no further knowledge to contribute on these topics.