Dietitians Australia

FSANZ P1056 Caffeine Review

Response to consultation
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Recipient

Food Standards Australia New Zealand

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[redacted]

About Dietitians Australia

Dietitians Australia is the national association of the dietetic profession with over 8500 members, and branches in each state and territory. Dietitians Australia is the leading voice in nutrition and dietetics and advocates for food and nutrition for healthier people and healthier communities.

The Accredited Practising Dietitian (APD) program provides an assurance of safety and quality and is the foundation of self-regulation of the dietetic profession in Australia. Accredited Practising Dietitians have an important role in supporting consumers to make healthy food choices, including the safe consumption of caffeine at different stages of life (e.g. during pregnancy and lactation, adolescence, etc.) and the use of caffeine as an ergogenic aid for performance enhancement.

This submission was prepared by members of the Dietitians Australia Food Regulation and Policy Advocacy Working Group following the Conflict of Interest Management Policy and process approved by the Board of Dietitians Australia. Contributors include Dietitians Australia members with wide ranging expertise in areas including public health, food systems, food industry, sports nutrition, and academia.

Summary

1. Dietitians Australia support 'Option 3: Hybrid mix of regulatory and non-regulatory approaches' as outlined in the Food Standards Australia New Zealand (FSANZ) 'P1056 first call for submissions Report' documentation.
2. The proposed changes to regulation should be supported by a comprehensive consumer education and awareness campaign, with key messages incorporated that explain the specific risks identified for each at-risk sub-population (including information for parents and caregivers of infants and pre-schoolers).
3. FSANZ should also consider the following in its proposal:
    - Caffeine advisory or warning statement design and placement.
    - Consistency between FSANZ and Therapeutic Good Administration Australia (TGA) on caffeine levels and advisory statement design.
    - Expand advisory and warning statements applicable to children to include adolescents.
    - Accuracy of product preparation instructions and requirement to provide appropriate measuring tools to promote consumption in safe amounts (e.g. providing smaller scoop for powdered products, requiring energy drinks containers to be resealable if containing more than one serve).
    - Requirement that international products include caffeine content on the label rather than stating "proprietary blend".
    - Potential for the Trans-Tasman Mutual Recognition Act 1997 (Cth) and Trans-Tasman Mutual Recognition Arrangement (TTMRA) between Australia and New Zealand to be used as a loophole to import highly concentrated caffeine products into Australia from New Zealand, even if the products would not be allowed for import to Australia from a different country.

Discussion

Questions for all 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.

Caffeine has a long history of use as a mild stimulant and is arguably the world's most commonly consumed psychoactive substance.[1] Caffeine is found naturally in a variety of foods, but the main dietary sources in the Australia population include coffee, tea, cocoa products (e.g., chocolate), and beverages such as cola and energy drinks.[2] Other 'non-conventional' caffeine sources (often manufactured for consumer convenience) also exist, including sports gels, chewing gums, powdered products, nasal/oral aerosols, and dissolvable mouth strips.[3] While Dietitians Australia considers most of these sources to contain levels of caffeine (<200 mg/serve) that are likely to pose low risk to consumers, concerns have been raised about the caffeine content of powdered supplements that are available in the consumer market; specifically, pre-workout supplements.[4] An independent assessment of the caffeine content of popular pre-workout supplements in Australia found some products contained (on average) up to 387 mg of caffeine in a single serve; with the average caffeine values ranging from 59% through to 114% of that reported on the product label.[4] Furthermore, analysis of samples from different depths (layers) of the product container revealed considerable within-product variability (7 of the 15 pre-workout supplements tested had ≥40 mg/serve difference between the layers).[4] In comparison to conventional food items like tea, coffee, and chocolate, some pre-workout supplements contain a dose of caffeine that likely exposes consumers to potential caffeine-related harms (including sleeping disturbance, anxiety, cardiovascular events, seizures, and death).[5]

The ergogenic capacity of caffeine has been well described,[6] with low to moderate acute doses (i.e. absolute doses of 40-200 mg or relative doses of 0.5-3 mg/kg body weight) demonstrating efficacy across a spectrum of cognitive tasks[7] and exercise modalities;[8] even after significant periods of sleep loss.[9] Thus, there is no scientific rationale for caffeine to be available in products at levels that far exceed this.

Formulated Supplementary Sports Foods have continued to gain popularity (even outside the athletic context and within the general population) since caffeine was removed as a banned substance under World Anti-Doping Agency (WADA) governance in 2004.[10] Given their popularity and wide availability in the consumer market, Dietitians Australia have concerns for the health and safety of individuals who may consume multiple sources/serves of Formulated Supplementary Sports Foods products in addition to habitual dietary intake of caffeine (i.e., via daily coffee/tea). Consuming multiple sources/serves of Formulated Supplementary Sports Foods in addition to habitual intakes from non-Formulated Supplementary Sports Foods could place consumers at risk of exceeding the recommended maximum daily level of 400 mg/day for adults.[11] Especially since caffeine clearance occurs relatively slowly, with a typical half-life reported as 5-6 hours.[12] This is even more prudent for caffeine sensitive populations,[13] who may be more vulnerable to harmful effects of caffeine.[11] Even at the elite sporting level, Sports Dietitians Australia recommend athletes seek advice from an Accredited Sports Dietitian to determine the lowest effective dose of caffeine to optimise performance but minimise any risk of side effects.[14]

Therefore, Dietitians Australia supports 'Option 3: Hybrid mix of regulatory and non-regulatory approaches' as outlined in the FSANZ 'P1056 1st call for submission Report' documentation. It is noted that this is also FSANZ's preferred option based on the need to consider the risk posed by

caffeine consumption in the wider food supply to the general population (including sensitive sub-populations), with further amendment of the Code to address that risk.

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, formulated caffeinated beverages and Formulated Supplementary Sports Foods, 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?

Dietitians Australia notes FSANZ's preferred Option is to prohibit caffeine being added to all foods apart from cola-type drinks, formulated caffeinated beverages and Formulated Supplementary Sports Foods; and that this measure would have no impact on the current ability under the Code to add caffeine-containing foods to other foods (e.g. adding coffee or chocolate to a cake or confectionery). Given these are the major sources of caffeine for Australian consumers, Dietitians Australia agrees that a pre-market assessment should be required to add caffeine to any other foods. This will ensure the consumer market is not overwhelmed with caffeine-containing products and better regulation of caffeine-containing foods available to the public.

3.Do you foresee any compliance or enforcement issues with the preferred approach of expressly permitting total caffeine in formulated caffeinated beverages and Formulated Supplementary Sports Foods 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 formulated caffeinated beverages?

Dietitians Australia does not foresee any major compliance or enforcement issues with the preferred approach. However, FSANZ should consider several aspects as part of its proposal:

- Greater consistency is needed between FSANZ and TGA on caffeine levels in products for oral consumption. FSANZ proposal is to explicitly permit total caffeine in Formulated Supplementary Sports Foods up to a maximum of 200 mg in a 'one day quantity' in conjunction with appropriate labelling requirements. However, the TGA indicates for listed medicines the maximum recommended daily dose must not provide more than 400 mg of total caffeine from all ingredient sources. The lack of consistency in messaging is likely to create consumer confusion.
- Further consideration for quality assurance of caffeine-containing products (and labelling) is needed at the manufacturer level; particularly with regard to powdered products. Recent research on the 15 most commonly consumed pre-workout supplements in Australia identified that only six of the pre-workout supplements quantified the amount of caffeine on the nutrition information panel;[4] and when batches of products were examined, the percent of caffeine present ranged from 59% to 176% of packaging claims. As such, consumers are likely to be exposed to large and variable caffeine doses if ingesting pre-workout supplements.

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

FSANZ should also consider the following in its proposal:

- Caffeine advisory or warning statement design and placement.
- Consistency between FSANZ and TGA on caffeine levels and advisory statement design.
- Expand advisory and warning statements applicable to children to include adolescents.
- Accuracy of product preparation instructions and requirement to provide appropriate measuring tools to promote consumption in safe amounts (e.g. providing smaller scoop for powdered products, requiring energy drinks containers to be resealable if containing more than one serve).
- Requirement that international products include caffeine content on the label rather than stating "proprietary blend".

- Potential for the Trans-Tasman Mutual Recognition Act 1997 (Cth) and Trans-Tasman Mutual Recognition Arrangement (TTMRA) between Australia and New Zealand to be used as a loophole to import highly concentrated caffeine products into Australia from New Zealand, even if the products would not be allowed for import to Australia from a different country.

Dietitians Australia also suggests that the proposed changes to regulation are supported by a comprehensive consumer education and awareness campaign, with key messages incorporated that explain the specific risks identified for each at-risk sub-population (including information for parents and caregivers of infants and pre-schoolers).

5. Can you share any further knowledge of current research about?

a. the health effects of caffeine,

The acute ergogenic properties and health effects of caffeine are well established.[6,15] Likewise, the safety profile of ingested caffeine has been well-documented; with evidence indicating that for healthy adults, caffeine consumption is relatively safe at a threshold of approximately 400 mg/day (and 100 mg/day in healthy adolescents).[11] However, there are known vulnerable populations (i.e., pregnant women, children, individuals with cardiac or vascular disease), and in addition to this, there may be individuals (i.e., the elderly or individuals with underlying medical conditions), who are not part of any vulnerable population but who, for genetic or metabolic reasons, may be susceptible to harmful effects.[16]

A recent review suggests that caffeine exerts biological effects with the potential to adversely affect bone mineral density:[17] however, the existing evidence is predominantly based on pre-clinical studies. Furthermore, a limited number of population-based studies suggest that in individuals at increased risk for the development of osteoporosis and fractures (e.g., older adults and especially post-menopausal Caucasian females), chronic caffeine consumption at levels equivalent to two or more cups of coffee daily (~200 mg/day) may affect bone metabolism and modestly raise the risk for osteoporosis and fractures.[17] However, further research is required to determine causal relationships, and it appears that caffeine at doses of <400 mg/day may not adversely affect bone metabolism.

The importance of the connection between caffeine consumption and sleep, particularly in adolescent populations should be considered. A study exploring the relationship between regular energy drink intake and sleep among adolescents demonstrated a negative correlation between energy drink consumption and meeting the recommended hours of sleep (in both males and females).[18] Energy drinks have become very popular, and because of their pleasing taste and wide availability, pose a risk to teenagers' ingesting high doses of caffeine. It should be highlighted that although FSANZ supporting documentation for this proposal indicate that energy drinks only contribute 4% to the dietary caffeine intakes of 13–19-year-olds, this information is based on data collected in the 'Day 1 of the 2011-12 National Nutrition and Physical Activity Survey (NNPAS)', and likely under-represents true dietary intakes in today's market. At a minimum, further education for children, parents, and teachers about the potential health risks of energy drink consumption and its association with sleep implications is needed.

Finally, Dietitians Australia is aware of a recent systematic review exploring the side effects of caffeine supplementation in sport, which indicated that the prevalence and magnitude of side effects with high doses of caffeine were habitually higher than with low doses of caffeine.[19] From a practical perspective, doses of 3 mg/kg body weight of caffeine were recommended for obtaining the ergogenic benefits of caffeine with the lowest prevalence and magnitude of side effects.

b. global developments in caffeinated food products, or

Dietitians Australia is unaware of any global developments in caffeinated food products.

c. regulatory approaches being taken in comparable markets?

Dietitians Australia is unaware of any changes to regulatory approaches in comparable markets, either internationally or nationally.

However, there are recent developments in restricting the sale of formulated caffeinated beverages to those under 18 years of age in Bridgetown (Western Australia). Poland's Sports Minister has also presented a bill that would ban the sale of energy drinks to those under 18 years of age. The threshold for caffeine consumption for adolescents is 100 mg/day. Hence Dietitians Australia recommends expanding advisory and warning statements applicable to children to include adolescents on Formulated Supplementary Sports Food.

Questions for stakeholders

11. How many stock keeping units (SKUs) will be affected by the proposed changes, for either Formulated Supplementary Sports Food.

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?

Dietitians Australia does not have comments on Questions 11-14

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

Green tea extract is being added to products such as formulated meal replacements and ketone shots because of its potential effect on fat oxidation and therefore weight loss.[20] However, the evidence for the use of green tea extract in aiding weight loss is inconsistent.[20-21] There are meal replacements and ketone shots[22-24] which contain green tea extract in the market that do not currently label that their products contain caffeine. The amount of caffeine found in green tea extract can vary greatly and these products should be included under this proposal.

16. Are there any unintended consequences of the proposal?

The lack of consistency between FSANZ and TGA on caffeine levels in products for oral consumption may create consumer confusion. The FSANZ proposal is to explicitly permit total caffeine in Formulated Supplementary Sports Food up to a maximum of 200 mg in a 'one day quantity' in conjunction with appropriate labelling requirements. However, TGA indicates for listed medicines the maximum recommended daily dose must not provide more than 400 mg of total caffeine from all ingredient sources. Consistency is needed between FSANZ and TGA.

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.

Dietitians Australia considers Option 3 to be the most effective option. For healthy adults, caffeine consumption has been shown to be relatively safe at a threshold of approximately 400 mg/day (and 100 mg/day in healthy adolescents). However, there may be vulnerable populations (i.e., pregnant women, children, individuals with cardiac or vascular disease), and individuals (i.e., the elderly or individuals with underlying medical conditions), who are not part of any vulnerable population but who, for genetic or metabolic reasons, may be susceptible to harmful effects from caffeine.[16]

Dietitians Australia strongly encourages FSANZ to consider:

- caffeine advisory or warning statement design and placement
- expanding advisory and warning statements applicable to children to include adolescents
- ensuring accuracy of product preparation instructions and requirement to provide appropriate measuring tools (e.g. smaller scoops to avoid over-consumption)
- requiring international products include caffeine content on the label rather than stating "proprietary blend".

Dietitians Australia also suggests that the proposed changes are supported by a comprehensive consumer education and awareness campaign, with key messages incorporated that explain the specific risks identified for each at-risk sub-population (including information for parents and caregivers of infants and pre-schoolers).

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

Dietitians Australia does not have further comments.

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