Complementary Medicines Australia SUBMISSION *to FSANZ:*

Urgent Proposal P1054 Pure and highly concentrated caffeine products

14 November 2019

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Complementary Medicines Australia

Complementary Medicines Australia (CMA) welcomes the opportunity to provide comment on the FSANZ – Urgent Proposal P1054 regarding pure and highly concentrated caffeine products.

CMA is committed to a vital and sustainable complementary medicines sector, and represents stakeholders across the value chain for products regulated as both foods and medicines, including manufacturers, raw material suppliers, distributors, consultants, retailers and allied health professionals.

We support the safe use of substances, foods and medicines, with access through appropriate risk-based regulation whilst still meeting consumer demand and a thriving, competitive business environment supporting Australia's economy and skilled and manufacturing jobs environment.

Consultation

On **1 November 2019**, Food Standards Australia New Zealand called for submissions by **14 November 2019** (10 business days).

While recognising there is urgency attached to this issue, we also note that a 2 week timeframe is an insufficient time for many interested stakeholders to respond, in particular, smaller businesses and consumers who may have a perspective to draw. Further, it is insufficient time for coordinating bodies including associations and other representative stakeholder forums to consult with their own member body to draw a fully informed and meaningful conclusion.

The limited timeframe will certainly limit the usefulness of the feedback received. We reserve the right to amend our position on these goods due to the timeframe.

Why is this consultation occurring?

The Australian Government are seeking options for strengthening regulations and consumer warnings in relation to pure and highly concentrated caffeine food products, such products posed an unacceptably high risk for consumers and, as such, there was a need to act to protect public health and safety. This has also recently occurred for therapeutic goods (medicines).

In August 2019, Food Standards Australia New Zealand (FSANZ) published a review titled 'Pure and highly concentrated caffeine products'. As noted in that document, it was in response to a request in July 2019 by the Minister for Aged Care and Senior Australians, the Hon Richard Colbeck and the Minister for Health, the Hon Greg Hunt, requested FSANZ provide information about current caffeine permissions in the Australia New Zealand Food Standards Code (the Code) and prepare preliminary recommendations

for strengthening regulations and consumer warnings in relation to caffeine powder and high caffeine content products.

On 1 November 2019, the Call for submissions – Urgent Proposal P1054 - INITIAL CONSIDERATION REPORT was published.

The consultation notes that, while The Code only permits or prevents caffeine's addition to or use in food in specific circumstances, highly concentrated forms of caffeine have not been expressly prohibited by the Code.

CMA notes the tragic and untimely passing of a young man from a very high unintentional overdose of a pure caffeine product. As far as we aware, it is not clear whether this product was originally purchased within Australia or was imported from an international e-commerce site. Certain safety concerns associated with the sale of highly concentrated caffeine products has been recognised in the United States by the Food & Drug Administration, although with limited regulatory action attached.

Current Standards, Regulations and Recommendations

Current domestic standards applicable to caffeine are:

- Standard 2.6.2 Non-alcoholic beverages and brewed soft drinks;
- Standard 2.6.4 Formulated caffeinated beverages;
- Standard 2.9.3 Formulated meal replacements and formulated supplementary foods;
- Standard 2.9.4 Formulated supplementary sports foods.

In September 2019 Minister Colbeck released the report and agreed to all recommendations made by FSANZ to enhance consumer safety with regards to caffeine powder and high content caffeine food, which in summary relates to:

- Prohibition of highly concentrated caffeine food products
- An expedited limit applied to caffeine limits for foods within Standard 2.9.4
- Consumer education campaign on caffeine safety
- Guidance on compliance actions for enforcement agencies
- Targeted research on consumption trends including vulnerable groups

Below are the recommendations in full:

Recommendation one: That FSANZ develop and declare as urgent a proposal to amend the Code to prohibit the retail sale of pure and highly concentrated caffeine food products.

Recommendation two: That FSANZ consider developing a maximum limit of caffeine in foods, based on the outcomes of the current review of Standard 2.9.4 – Formulated Supplementary Sports Foods. This work could be expedited, or the caffeine component could be separately progressed pending resources.

Recommendation three: That a coordinated inter-agency consumer information campaign on safe caffeine consumption be developed and implemented in conjunction with the implementation of recommendation one, if adopted.

Recommendation four: That, prior to or in parallel with the consumer information campaign, guidance on the regulation of products containing pure or high concentrations of caffeine, and high caffeine content products, be developed by Implementation Subcommittee for Food Regulation (ISFR) for, and agreed by, enforcement agencies to inform compliance action.

Recommendation five: That targeted research on caffeine consumption across the Australian and New Zealand population, including consumption by specific vulnerable population groups, continue to be undertaken, including as part of the upcoming Intergenerational Health and Mental Health Study.

Key regulatory proposal:

The key regulatory restriction of proposal (P1054) is to amend Standard 1.1.1 related to requirements for food sale by restricting the percentage of permissible caffeine levels in food. It aims to address recommendation 1, by limiting any food included in a food standard to a **maximum caffeine content of 5% in the final product**. This proposal essentially imposes a condition of sale which will capture caffeine in all food forms in a retail environment. Therapeutic good requirements will be separately captured by the Permissible Ingredients Determination (4% in undivided preparations > later decreasing to 1%), as well as those specified by the final Scheduling decisions that are currently under consideration in the Scheduling Policy Framework.

CMA notes this regulatory action, with the allowances to wholesale trade that this allows, whilst reducing the risk at the wholesale interface. However;

CMA registers the following potential issues regarding this action:

a) The amount is greater than that in the proposed scheduling amendment of 4% in undivided preparations and a maximum recommended daily dose of 600mg. While retail products should be harmonised, the 5% limit is more supportable than the lower limits.
b) The amount is greater than the recent TGA changes to be made with immediate effect to

caffeine containing medicines: undivided preparations must contain not contain concentration of total caffeine greater than 4%, until March 2021, after which they must not contain caffeine at a level greater than 1%. CMA preferentially supports the 5% limit proposed by FSANZ for all retail goods.

c) The FSANZ amendment does not capture or account for imported product, in particular that imported for personal use. However we note this may be addressed through other Governmental actions and education campaigns.

d) It does not prohibit any goods imported under the Trans-Tasman MRA, as there are not prescribed maximum caffeine levels in the *New Zealand Food (Supplemented Food) Standard 2016*.

Items a) – b) indicate an uncoordinated regulatory response, and while CMA commends FSANZ's well researched response and report, we highly encourage better collaboration between the agencies, and in particular that the TGA should wait to harmonise with FSANZ and similarly provide improved research reports.

Items d) and e) suggest that many products with a much higher percentage that 5% are able to be easily accessed, particularly those for personal importation.

Food-medicine Interface

The scheduling proposal exempts food preparations, including therefore dietary supplements. Whilst this may be advantageous for food manufacturers, it has the potential to further widen the gap between the regulation of foods and medicines, creating inconsistency and a lack of consistency across the domestic marketplace, potentially creating more opportunities for accidental exposure to dangerous substances.

There is a key concern that the excessive restriction of caffeine in either foods or therapeutic goods could increase either the legal or illegal importation of similar substances that have a far more dangerous profile than caffeine. It is more protective of consumers to allow their demands to be met by safely but reasonably regulated products, both foods and therapeutic goods, than to restrict them to the degree that black market and/or personal importations of less products is encouraged.

CMA recommends that FSANZ collaborate with the TGA and peak industry bodies to arrive at a consistent and unified approach immediately and into the future.

Imported products

In the August 2019 Risk Assessment Report published by FSANZ, its reported that the amount of imported product considered to be for personal use was lowered from 10kg to 1kg by amending the regulations to the Imported Food Control Act 1992 (the IFC Act). Any amount below 1kg is exempt.

However an October update to the FSANZ website for this report notes that food arriving vial the mail pathway is out of scope of the Food inspection Scheme.

The report also noted that the Department of Agriculture asked FSANZ to conduct a risk assessment report on imported sports supplements that may contain caffeine. The results of which may increase inspection rates at the Australian Border. The October proposal does not report back on this risk assessment.

Summary Position

Due to the short consultation period, we reserve the right to amend our position if other relevant information becomes available.

- This proposal addresses some of the immediate risk posed to consumers by concentrated caffeine containing foods, which is a sensible approach to appropriate regulation to ensure that accidental severe overdoses or deaths do not occur from products purchased in Australia.
- However, it does not sufficiently mitigate accessibility through import pathways, especially for personal use as controls at the border do not monitor this highly utilised consumer import pathway.
- Potential risks of overregulation through excessive restriction of caffeine, an in-demand product from consumers, are that consumers will instead revert to personal importations of either legal but significantly more concentrated or illegal substances. This is relatively easy to do through international e-commerce websites. Therefore, regulatory restrictions must be balanced with consumer demand in order to have the most positive net impact on health and safety.
- FSANZ proposes a 5% restriction on Australian retail food products, with attendant cautionary messages. We believe that this is the preferential option and a more reasonable regulatory proposition that the Therapeutic Goods Administration proposals or regulations of between 1% and 4% in undivided preparations such as powders and liquids.
- There are remaining issues of clarity for stakeholders at the food-medicine interface. CMA encourages the TGA in particular and also FSANZ to coordinate and collaborate more effectively on these shared issues. This enable a much clearer, more sensible, and easy to navigate regulatory landscape for both consumers and businesses.