Project Officer Proposal P1056
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Tēnā koe,

Proposal P1056 – Caffeine Review (1st Call for Submissions)

Thank you for the opportunity to comment on this Proposal.

New Zealand Food Safety (NZFS) provides its preliminary support for FSANZ's preferred option, *Option 3 – Hybrid mix of regulatory and non-regulatory approaches*, which includes the following proposed regulatory measures:

- A new express permission to add caffeine to formulated supplementary sports foods (FSSF), with total caffeine up to 200 mg in a one-day quantity;
- An express prohibition on the addition of caffeine to foods for retail sale, other than for those foods that have a specific permission (i.e. cola-type drinks and formulated caffeinated beverages (FCBs)); and
- The removal of the P1054 variation (i.e. 1.1.1—10(5)(g) of the Food Standards Code).

We note that drafting of the proposed variations to the Food Standards Code will be provided in the 2nd CFS, at which point NZFS will be able to comment fully on the implications of the proposed approach.

We agree that reference to 'caffeine' in this Proposal should encompass all sources of caffeine, which may be added to foods as the extract from a plant or as the chemically synthesised or purified form.

Risk assessment

NZFS commends FSANZ on the thorough risk assessment that underpins this Proposal. The following comments are made with the view to further strengthen the four assessments:

Safety assessment (SD1)

The safety assessment provides a useful and comprehensive summary of the toxicology of caffeine. The spectrum of effects and dose thresholds are all well supported by the presented evidence. From the case studies described, and from numerous sections in the document, it is apparent that the safety of caffeine is often related to a public health awareness/perception issue that seems to include a belief that caffeine's desired effects can be enhanced by unlimited increases in dose, leading in some cases to acute toxicity. Any upward trends in these sorts of cases should be monitored, and if increasing, may require reconsiderations of the standard and/or partnering with public health agencies to develop public health messaging about the need to balance benefits and risks to reduce high dose caffeine intoxications. It is unrealistic to presume

that the typical consumer would be aware of their own individual daily mg/kg caffeine intake during any particular day, and would argue in favour of the preferred option of requiring premarket assessments of foods containing caffeine.

Our specific comments on SD1 that we recommend are addressed in the 2nd CFS are:

- On page 4 'Conclusions', it states that there is insufficient evidence to provide recommendations to breastfeeding women. Yet later in the supporting document (section 2.6.3.3), it is recommended that women in the perinatal period should continue caffeine intake to avoid withdrawal symptoms. This could be inconsistent with the earlier conclusory remark since presumably perinatal and breastfeeding would be synonymous periods for many women.
- Section 2.6.9.3 – suggest specifying the effect from Krebs et al. 2012.
- The conclusions in Section 2.8, as currently worded, leave it ambiguous what the point of departure dose should be for risk assessment (i.e. 1.4 vs 3.0 vs 5.7 mg/kg/day). Suggest this is more directly stated. While this doesn't impact the bottom line conclusions, it would be beneficial for clarity.

Dietary intake assessment (SD2)

NZFS supports the methodology and conclusions of the dietary intake assessment.

We note the consumption data used in the Dietary Intake Assessment is from 2011/12 for Australia and 2008/09 for New Zealand, and as such is not necessarily reflective of the changes in caffeine consumption over the last 10-12 years. However, we do not consider that more up-to-date consumption data would affect FSANZ's overall proposed regulatory approach under this Proposal.

Recent work from the US National Health and Nutrition Examination Survey (NHANES) provides some assurance regarding dietary intake patterns of caffeinated beverages which did not substantially change between the years 2013-2016[1]. Of note, is that the percentage of energy drink consumers remained relatively low in the overall population, and amongst children. Furthermore, analysis was conducted looking at hourly and daily patterns of consumption which showed there was no clustering of caffeinated beverage consumption events over short periods.

The CFS noted that New Zealand specific data for caffeine intake among children was not available, and subsequently the reasonable assumption that caffeine intakes of New Zealand children are the same as that of Australian children was made. As noted in the report, work on the caffeine intake of children from the New Zealand Children's Nutrition survey was published in 2010 and referenced in the supporting document.

Future national nutrition survey data from Australia and New Zealand could be used by FSANZ to inform the premarket assessment of any future applications seeking to amend the Food Standards Code to add caffeine to other foods. Planning for the next New Zealand National Nutrition Survey is underway and this survey will gather data on caffeine consumption in the New Zealand population aged two years and above. It would be useful for FSANZ to specifically consider the proportion of consumers of caffeine in the surveys and their daily caffeine intakes per day and by body weight.

Social science assessment (SD3)

NZFS supports the findings of the social science assessment with the following comments:

We suggest the finding "There was no evidence of overconsumption of caffeine in children based on Australian/New Zealand studies." is reviewed. One study suggested that at least some 8–12

[1] Benson S.M. et al. Hourly and daily intake patterns among U.S. caffeinated beverage consumers based on the National Health and Nutrition Examination Survey (2013-2016). Food and Chemical Toxicology. 2019:125(271-278)

year old South Australians were consuming caffeine over the recommended daily maximum (>120 mg/day), although the exact number was not mentioned in the study. In addition, this finding is not based on New Zealand studies as there were no studies available about the caffeine consumption of children in New Zealand.

NZFS is aware of a recently published market research report from Euromonitor International. Although the market research does not investigate consumer behaviour directly, the research provides information on sales of energy drinks in New Zealand. The report *Energy Drinks in New Zealand* (Euromonitor International, 2022) showed that the off-trade (i.e. general retail) sales of energy drinks in New Zealand increased from 25.3 million litres in 2017 to 33.6 million litres in 2022 (32.8% overall growth). The sales volume of energy drinks was already rising steadily pre-pandemic and continued to grow during the pandemic, with the strongest growth for the reduced sugar variants. According to the report, consumption of energy drinks skews very strongly towards the younger demographic, with university students a particularly loyal cohort.

Assessment of caffeine and sports performance (SD4)

The scope of the literature review was relatively narrow with a focus on the effect of caffeine intake on time-trial performance in sports including cycling, running, rowing and swimming. It was concluded, with a low level of certainty, that caffeine has a small beneficial effect on time-trial performance.

We note that research published after August 2017 was not included due to the method of study selection, and consider this should be mentioned upfront in the report (currently in the appendix to SD4). Also, while FSANZ suggests that it is unlikely that subsequent research would change the effect sizes in a meaningful way, we consider there are other benefits of including an updated search (Aug 2017 - ~2022), such as newer studies may alleviate some of the identified limitations (indirectness, risk of bias).

We also consider it would be helpful to explain (in section 1.4.6) the implications of the limitation *indirectness*, i.e., that the true effect may be different than the estimated effect *for groups that were minimally represented in the studies, such as women and non-trained people*. This is relevant because it is possible that more recent studies may address this limitation. It is acknowledged as a limitation in other systematic reviews, so it is possible that recent or current studies will fill this research gap.

Prohibition of caffeine in other foods

NZFS supports the rationale provided in section 3.2.2 to propose a general prohibition on the addition of caffeine to all foods for retail sale unless expressly permitted elsewhere in the Food Standards Code. Noting that this approach would then require an application to FSANZ and a premarket assessment if a food business wished to amend the Code to add caffeine to other foods in the future.

This approach will help to appropriately manage caffeine levels in the food supply (rather than widespread use), and to manage the associated safety risks for population groups of exceeding the recommended maximum limits of caffeine. We are in favour of case-by-case premarket assessments, including a full dietary intake assessment, for future proposed uses of caffeine in foods *(relates to Q2 in CFS)*.

<u>Draft variation to the Food Standards Code</u>

In drafting the prohibition in the Food Standards Code, NZFS considers it important to ensure that:

- Reference to 'caffeine' relates to all sources of caffeine, including synthetically produced or from a plant source (e.g. guarana, green tea extract, green coffee bean extract).

- The current general prohibition on the use of a novel food will apply to novel plant sources of caffeine, and therefore a pre-market safety assessment would be required before approval for use.
- The current provisions allowing the sale of coffee, teas and chocolate that naturally contain caffeine are retained.
- The current ability to add compliant caffeine-containing foods to other foods (e.g. adding chocolate to a cake or coffee to a milk) is retained.

It is also important to ensure that not only does the Food Standards Code regulate caffeine added to food, but also caffeine as a pure concentrated product. We note the wording used for the preferred regulatory approach is a prohibition on the *addition* of caffeine to foods alongside the removal of the P1054 variation. We are concerned that this approach may not adequately prohibit the sale of pure caffeine products and encourage you to consider this when drafting the amendments to the Code.

We also wish to draw your attention to the need for clarity in the Code to determine when coffee, tea or chocolate are no longer a compliant caffeine-containing food that can be added to another food. We note products on the market that use coffee extract as a flavouring and cold brew products that contain cold brew coffee concentrate. We encourage you to consider this matter when drafting the amendments to the Code.

Current market

We also consider that the general prohibition will provide certainty for industry and enforcement agencies as to the exact permitted uses of caffeine in foods and the sources of caffeine that may be used.

Under current regulations there is some uncertainty and we have observed products other than FCBs, cola-type drinks and FSSF on the market that contain added caffeine. In some cases, these products use less known caffeine-containing ingredients (e.g. green tea extract) without any appropriate labelling to ensure the consumer is aware the product contains caffeine.

Product examples include a kombucha product with both naturally-occurring caffeine and added caffeine from green coffee bean extract, a chewing gum with added pure caffeine, an instant coffee product with added guarana extract, green tea extract and green coffee extract, and protein bars with added green coffee and/or green tea extract. We are also aware of products that stack multiple caffeine-containing ingredients in a product but total caffeine in a serve is not declared.

While some of the above products may be impacted by this Proposal *(relates to Q15 in CFS)*, we note that data gathered by NZFS using the GS1 On Pack database suggests there are relatively few general foods (other than FCBs, cola-type drinks and FSSF) that contain added caffeine currently sold in New Zealand. Most products containing added caffeine are cola-type drinks and FCBs. Other products typically contain small amounts of naturally-occurring caffeine due to the presence of coffee as a flavouring agent (e.g. iced coffee drinks, coffee flavoured ice cream) or because they are fermented from tea (e.g. kombucha).

Also, we note that some non-cola soft drink products now position themselves as FCBs, we assume to make use of the caffeine permission, but do not contain any listed substances also permitted in FCBs. This appears to be a workaround for non-cola type beverages to contain caffeine like their cola-type counterparts. We consider this may be an unintended use of the FCB provisions and that a dietary intake assessment may not capture the potential increase in caffeine intake through this use.

Permission for caffeine in Formulated Supplementary Sports Foods

NZFS supports the proposed approach to provide a new express permission to add caffeine to FSSF, with total caffeine up to 200 mg in a one-day quantity, alongside appropriate labelling requirements.

As well as protecting public health and safety, this approach recognises the small beneficial effect of caffeine on sports performance (as presented in SD4) and the global use of caffeine in sports food products.

Labelling for Formulated Supplementary Sports Foods with added caffeine

NZFS supports the rationale and proposed approach to require an advisory statement using wording to the effect of 'contains caffeine' on the label of all FSSF containing caffeine, irrespective of the source or amount. This approach is consistent with the advisory statement currently required on cola-type beverages and FCBs.

We also agree with the rationale and proposed requirement for caffeine-containing FSSF to declare the average quantity of caffeine present in the nutrition information panel (NIP), as detailed in the CFS. We recommend FSANZ considers applying this same rationale to FCBs and to consider a further amendment to the Code to require caffeine to be declared *in* the NIP and not adjacent or following it as currently required for FCBs.

In addition, we consider the requirements for an advisory statement and caffeine content information in the NIP will help to inform consumers about the caffeine content of foods, where currently some consumers may not realise a product contains caffeine if less known caffeine-containing ingredients (such as green tea extract) are used.

One-day quantity

NZFS agrees that requirements to declare the caffeine content in the NIP in conjunction with the statement of recommended consumption in one day (2.9.4—4) should enable enforcement of the proposed maximum per one-day requirement.

As safety concerns associated with excessive intakes of caffeine is the primary basis for setting a one-day quantity for caffeine in FSSF, we recommend FSANZ considers if a restriction on the package of a FSSF could be applied in some way so that a package of a ready-to-use product cannot contain more than a one-day quantity. This practise is observed in some ready-to-use FCBs that are packaged in volumes greater than the labelled recommended daily consumption. We are aware of a FCB product presented in a 'multiserve' screw top can with a total volume of 710 mL and a recommended maximum daily consumption of 500 mL, though a consumer could easily consume the whole contents of the package in a single day.

Health claims for Formulated Supplementary Sports Foods

NZFS agrees with FSANZ's approach to not amend the current provisions in the Food Standards Code for claims as they apply to FSSF under this Proposal – and to instead review this aspect under Proposal P1010 (Formulated Supplementary Sports Foods).

As noted in the CFS, the prohibited representations provision in 2.9.4—7 will apply to FSSF with added caffeine, and an express or implied representation that relates caffeine to enhanced athletic performance or beneficial physiological effects on sports foods could not be made. For clarity, we consider it important to note that this prohibition applies to all health claims, including self-substantiated claims, if that is the intent.

In addition, we consider it should be explicit in the Food Standards Code whether claims (including self-substantiated claims) for caffeine and health effects other than enhanced athletic perfo rmance

or beneficial physiological effects are permitted (e.g. caffeine and mental performance) ; given the broader definition of 'health effect' in Standard 1.1.2. If these claims are not permitted then we consider FSANZ should provide justification, otherwise it could limit innovation and create questions around implementation.

Impact on the *New Zealand Food (Supplemented Food) Standard 2016*

As noted in the CFS, part 1.9 of the *New Zealand Food (Supplemented Food) Standard 2016* (Supplemented Food Standard) currently permits supplemented food to contain caffeine for a purpose other than as a food additive. An advisory statement and nutrition information must be provided on the label of a supplemented food if the food contains a greater level of caffeine than is required to achieve a technological function under conditions of Good Manufacturing Practice.

It is also important to note that while the Supplemented Food Standard does not currently specify a maximum permitted level for caffeine in supplemented foods, the current provision in Standard 1.1.1—10(5)(g) of the Code applies to supplemented foods.

NZFS are currently considering the implications of the regulatory measures proposed under this Proposal on the current caffeine provisions in the Supplemented Food Standard.

Thank you for the opportunity to comment on this Proposal. We look forward to reviewing the proposed draft variations as part of the 2nd CFS. In the meantime, please contact us if you would like to discuss any points made in this submission.

Nāku noa, nā