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To whom it may concern,

P1010 – Formulated Supplementary Sports Foods - Submissions

These submissions have been prepared on behalf of a multinational food and beverage supplier that engages in both large-scale manufacturing and importation of products for sale in Australia. These submissions may be published as provided, unredacted, but have been prepared on an otherwise anonymous basis.

This document sets out our proposed submissions in response to P1010 – Formulated Supplementary Sports Foods and, particularly, the questions raised in the consultation paper released by FSANZ, published here: https://www.foodstandards.gov.au/code/proposals/Pages/P1010.aspx.

A. Market Overview

Q1. For industry or regulators, do you have market or product data or information that you would like to provide to update FSANZ's understanding of the current market in Australia, New Zealand or globally?

We engage regularly with consumers in Australia and in key foreign markets in order to better understand their consumption patterns, their wellbeing needs and what they are seeking from the food and beverage market. The expanding demand for functional food and beverages that support nutritional and lifestyle based aspirations is a key theme from the consumer feedback.

Market research in Australian markets shows that the consumer conception of health and wellbeing has evolved from purely physical to holistic wellbeing, and that there is a strong demand for additional nutritional support for 'active lifestyles' amongst consumers who are not professional/competitive athletes but who are still consuming FSSFs and supplemented foods in satisfaction of that demand.

1. Australian sales data analysis:

(a) The functional beverage sector exploded in popularity in 2022, setting to double in 2023 (https://www.goodfood.com.au/eat-out/news/fact-or-fizz-sales-of-soft-drinks-with-health-benefits-boom--but-are-they-actually-good-for-you-20230224-h2a32u).

(b) The IBIS World Report into Functional Beverage Production in Australia finalised at the end of 2022 (https://www.ibisworld.com/au/industry/functional-beverage-production/5502) found that:

i. the market size for Functional Beverage Production in Australia is currently set at $491m.

ii. The Functional Beverage Production industry is forecast to continue growing over the next five years, although intense competition is projected to limit this growth.

iii. Continued awareness of healthy lifestyles post-pandemic is likely to increase consumers' focus on immune health support food and beverages.

iv. Consumers are forecast to continue shifting away from soft drinks with high sugar content, supporting the industry.

v. While energy drink product innovation is projected to slow, new tastes and functionalities are likely to continue capturing consumer.

2. Key consumer demand data points re: wellbeing and performance:

(a) "Sports" performance nutritional support remains a relevant need for a specific group of Australians (13%). However, demand for nutritional support for "active lifestyles" far exceeds a purely sport-focused performance support demand; globally, functional drinks are expanding far beyond sport in response to consumer demand for better-for-you drinks to satisfy multiple wellbeing needs (https://www.winsightgrocerybusiness.com/center-store/better-you-beverages-hit-key-consumer-demands-health; https://www.foodnavigator-asia.com/Article/2020/06/19/Better-for-you-beverages-How-functional-drinks-are-fizzing-while-carbonated-and-energy-sectors-fall-flat).

(b) In the context of nutritional support for 'every day' performance, consumers have most commonly reported a strong desire for supplemented foods and beverages specifically supporting the following wellbeing markers: energy (feeling energised) (36%); mood/emotional and psychological regulation (35%); and immunity (23%) (*qualitative market research conducted via ResearchBods, June 2020)*. This clearly extends beyond the key support areas identified in the current S 2.9.4 of carbohydrates, protein, and caloric energy.

(c) Consumers recognise that optimising performance and wellbeing must be approached holistically. The requirement for additional nutritional support extends beyond physical health to emotional and psychological health and wellness and, even in the physical or physiological support category, consumers recognise that active lifestyle support needs differ depending on sex, stage of life, and other key factors.

vi. A wide range of needs that make up consumers' understanding of wellbeing includes 'female health' needs, including menopause, PMS, and Pregnancy Support (*ResearchBods, June 2020*).

vii. Consumers seek convenient methods of getting nutrients and vitamins through supplements (and supplemented foods) in an aim to focus on maintaining good health and wellness as a preventative/protective health measure (*Euromonitor Health and Nutrition Survey 2019* https://www.aquae-officiel.fr/wp-content/uploads/2017/11/Actu-EUROMONITOR-SurveyHealthNutrition.pdf).

viii. Consumers value holistic wellbeing, encompassing physical, emotional, and social wellbeing, over simple exercise and diet regulation (*ResearchBods, June 2020*).

ix. Mental wellbeing is the most prominent factor on holistic wellbeing, with consumers definition being "healthy" most commonly (more than 60% of respondents) as (a) mental well-being, (b) feeling "good", and (c) getting enough sleep (*Euromonitor Health and Nutrition Survey 2019*).

B. Definitions

Q2. As a consumer, regulator or industry stakeholder, have you identified any issues resulting from the definitions in the Code? If so, what are they and why are they an issue?

As outlined in our response to Q1, the current food and beverage classifications allowing for fortification with nutritive substances are not adequately evolved to address consumer demand for and understanding of what is known in the industry as the "functional" foods and beverages category. The definitional requirements in other categories, including Formulated Caffeinated Beverages and Formulated Beverages, are inconsistent and illogically restrictive, which currently forces innovating suppliers to look to the FSSF category as comparatively more relaxed in relation to hurdle compositional requirements. An example of these inconsistencies is the requirement that Formulated Beverages be non-carbonated, which does not seem to have any bearing on whether (from a safety or quality perspective) it is appropriate to be adding nutritive substances to such a product.

However, the category description "Formulated Supplementary Sports Food" is itself out of step with consumer demand and expectation in relation to functional foods and beverages, as is the description of products in this category as "specifically formulated to assist sports people in achieving specific

nutritional or performance goals". Our market research suggests that the requirement to include the "Formulated Supplementary Sports Food" product description on label may be confusing and off-putting to consumers who seek out functional beverages to support active, healthy lifestyles and general performance and wellbeing but do not self-identify as athletes.

The current prescriptive definitional requirements across formulated foods categories creates a regulatory framework that is difficult for innovating suppliers to navigate and results in increased (and sometimes prohibitive) compliance costs and restraints on otherwise safe and profitable new product development. This increased cost factor motivates many suppliers in this space to make use of alternative legal paths to market including the TTMRA, which means jobs and manufacturing spend that could be an investment in the Australian F&B manufacturing sector instead moved offshore.

Q4. For all, should the Code retain the existing definitions in Standard 2.9.4? If so, why and if not, why not?

We support the contention that consumers who are not elite or professional 'sports people' could and should also be considered an essential part of the target audience for a revised iteration of the FSSF category. We propose that the FSSF category should be restructured as a Formulated Functional Foods category, encompassing products 'specifically formulated to support people in achieving nutritional and performance goals' or 'specifically formulated to support active lifestyles'. This category could then also integrate Formulated Beverages, Formulated Caffeinated Beverages, and Electrolyte Drinks more comprehensively and consistently. It is essential, noting the impracticalities, restraints, and costs consequences highlighted in our response to Q2, that the definitions and hurdle requirements in relation to the FSSF category should not be made more any restrictive in revised iterations.

Our market research (*ResearchBods, June 2020*) regarding trends in this space shows that the idea of being "healthy" and "well" has evolved from the purely physical to a sense of holistic wellbeing that includes obtaining adequate nutrition to support not only in-the-moment exercise but sleep, weight maintenance, energy levels across the day, stress and mood management, and neurological function. All of these aspects are recognised as important in supporting both general wellbeing and specific performance.

"Functional" is the category description commonly used in the industry and has high recognition amongst consumers. The broadened category of food nutritionally formulated to support particular functionality and performance for people who may engage in various activities and have various support needs (rather than only people who identify as athletes) aligns more clearly with current and anticipated future market demand as well as consumer understandings of nutrition, health, and wellness.

Formulated Supplementary Foods (and Formulated Meal Replacements) could be retained as a separate category to distinguish foods that are formulated to address specific nutritional/dietary deficiencies and as a support to recovery from illness, health improvement (including weight loss), and nutrition needs for people with specific medical conditions from foods that are formulated to support performance and normal active lifestyle nutrition needs.

We consider that a definitional change of this kind would provide for greater clarity for both consumers and suppliers in the food-medicine-interface space. The distinguishing factors would remain: (a) form – a form ordinarily consumed as food, not a pill or tablet, (b) representations – no therapeutic purpose or claims permitted, and (c) formulation – no high-risk non-traditional food substances used as ingredients (with reference to the expanded TGA substances lists for deemed sports supplements. However, considering the presumption of regulation as a food that arises where a product falls within the definition of a specifically regulated food (and is not otherwise specifically determined to be a therapeutic good), clarification of a category of Formulated Functional Foods would provide certainty and streamlined paths to market for innovative and safe food products.

C. Compositional Permissions

Q5. Would a tiered approach to regulation based on composition improve public health and safety for consumers, while allowing for innovation (e.g. provisions for 'high risk' substances, restriction on sale, differing labelling requirements or compositional deviation)? If so, how could it look? How could high, medium and low risk products be differentiated? What requirements could apply to each and why (e.g. pre-market assessment, compositional and labelling requirements)?

See our response to Q4 for comments regarding a proposed change to Formulated Functional Foods as a high-level categorisation.

We consider that a tiered approach to regulation based on composition within this revised category would provide greater clarity (and ultimately better public health outcomes) for consumers and for suppliers (resulting in reduced compliance costs and more consistent compliance across the industry). Regulation of fortified foods and beverages, and specifically "functional" foods (formulated for specific nutritional purposes to support specific function/performance), based at least in part on composition (low or high risk nutritive substances) could facilitate:

(a) Streamlined new product development pathways at a lower cost for products manufactured in Australia, leading to increased investment in the Australian F&B manufacturing sector.

(b) Products better formulated to specific nutritional and performance needs of consumers, reducing risk of negative health outcomes from 'stacking' and general over-consumption.

(c) Improved nutrition and health outcomes for consumers due to the ability to consume additional necessary nutrients as part of a normal diet (with potentially increased direct benefits of consumption with/as food, as opposed to the consumption of supplements in isolation).

(d) Improved consumer awareness of the risks of consuming excessive amounts of certain substances and of consuming high-risk substances generally.

(e) Lower cost fortified food products for consumers, where cost of living and food in particular is likely to continue to increase in Australia in future over at least the short and medium term.

High-risk substances would reasonably include those that carry negative health outcomes when consumed above a certain maximum volume, consumed in a certain way, or consumed together with other substances. These factors may also determine that a substance is 'medium risk' depending on the nature of the outcomes or the complexity of the directions for consumption required but it may only be necessary to create a binary high/low risk categorisation. Low-risk substances would likely be those unlikely to cause negative health outcomes if consumed by *any* person at any practical volume, including children and pregnant women.

The stratification of nutritive substances based on risk would allow manufacturers to select for low-risk only substances more easily, which should positively influence the proportion of products on the market containing low vs high-risk substances whilst still allowing informed consent from consumers who choose to consume higher-risk substances in their food because the benefit is material to their interests.

In determining whether a substance is high, medium, or low risk, FSANZ could either implement a pre-market assessment process with reliance on existing health data from the TGA and other relevant regulators. Alternatively, and preferably, these categories could be defined not by the listing of specific substances in a Schedule but with a description of the criteria of assessment for low-risk vs medium or high risk and references to external standards like the World Anti-Doping Association's Prohibited List (similar to the approach for regulation of flavouring substances as additives at GMP). A determination process like that employed by the TGA and by FSANZ in relation to novel foods could mean that a substance is low risk if it meets the general criteria and is not specifically listed as a high or medium risk substance (though those lists may not themselves be exhaustive). As an intermediate measure, FSANZ could consider a self-substantiated notification system like that employed for health-claims as a part of the process.

While the primary aim is to ensure adequate protections for consumer health and safety, introducing greater flexibility in the identification and use of nutritive substances at the low end of the risk spectrum

would be highly beneficial to suppliers manufacturing in Australia and allow for easier importation pathways (and hopefully reduce the number of non-compliant and unsafe products being imported into Australia in the absence of sufficient supply to meet growing demand). A risk-based classification approach to permitted nutritive substances, not requiring specific listing for (at minimum) low-risk substances, would allow the regulation of fortified foods and beverages to effectively adapt to the pace of innovation for substances popular for supporting health and wellbeing, whilst optimising consumer protection and education in this space.

This compositional risk-based approach could appropriately be reflected in and result in not only more effective maximum volume limits but more effectively tailored declarations and warnings. Products incorporating only low-risk nutritive substances should not be required to bear warnings of any kind. The generalised warnings currently applicable to FSSFs, "Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision" would logically not apply. Instead, the direction to use under supervision might be a warning reserved for products containing high and medium risk substances.

Q8. How could the Code assist in reducing the risk to consumers who are stacking sport food products and potentially consuming more than the maximum amount permitted by Standard 2.9.4 in the Code?

FSANZ should consider:

(a) **One Day Quantity:** This concept may be desirable to retain as a reference only to *effective* consumption of serves of a specific food product to achieve desired goals, but as individual needs and goals differ significantly this is not generally considered by industry to be a useful or informative metric. It is not well understood by consumers in a food context and creates confusion with dosage directions for medications and what the direction actual means for the consumer's health and safety.

(b) **Safe consumption limit disclosures:** Identifying safe maximums for substances based on daily consumption or cumulative consumption across another relevant period would allow this information to be communicated effectively to consumers, e.g. via a % Maximum Safe Daily Intake labelling disclosure requirement. This disclosure should only be required for substances that are identified as having a safe maximum daily/cumulative consumption volume, but would otherwise fit easily within current labelling protocols and reduce the burden on the consumer to do the detective work in determining how much they are consuming across all the serves of food they consume in a day.

(c) **Specific warnings:** Warnings should be specific to the substances added to a product as far as is possible. For products containing high risks substances, suppliers could be required to label their products with a warning explaining the specific effect of consumption above recommended limits or inconsistent with use directions. Medium-risk ingredients might attract a general warning regarding medical supervision or caution around excessive consumption. Classification based on risk and the identification of specific high or medium risk substances means a greater capacity to apply tailored warnings (or elect not to use that substance if the warning is undesirable). Specific warnings can be mandated only on the basis of actual volume (like the laxative effect warning for sweeteners) or would perhaps better be applied wherever a maximum safe consumption limit disclosure is required.

An example of a currently permitted nutritive substance that is known to have negative health effects when consumed above certain volumes and/or for long periods is Vitamin b6. When stored in excessive levels in the body, Vitamin b6 can cause a consumer to experience symptoms of peripheral neuropathy (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8483950). The concern is that peripheral neuropathy cases have now been linked anecdotally not only to excessive daily consumption but to more moderate long-term consumption. Many consumers are not aware of this potential negative heath outcome and are not tracking their cumulative b6 consumption across the range of medications and food products they are consuming. The TGA warning regarding symptoms of peripheral neuropathy has been revised and is now required at 10mg of pyridoxine (a component of Vitamin b6) rather than the previous 50mg (https://www.tga.gov.au/news/safety-updates/peripheral-neuropathy-supplementary-vitamin-b6-pyridoxine). Currently, the max claimable Vitamin b6 volume in Formulated Supplementary Sports Foods is 3.2 mg in a one-day quantity and no maximum volume applies. FSANZ has not yet revised the regulation of Vitamin b6 in response to the changes made by the TGA, perhaps because the process

by which the Schedule can be changed is not well adapted to support fast or responsive changes. If assessed, based on the TGA regulatory position, it seems likely that Vitamin b6 would be classed as medium or high risk because there is an identified unsafe consumption level. If positions like those suggested above were implemented under revised regulation, products containing added Vitamin b6 (or more than a certain volume) could be labelled:

1. with a % of maximum safe [daily] intake in the NIP; and

2. with a tailored warning, e.g. “consumption of Vitamin b6 above max safe daily quantity may cause weakness, numbness, and/or pain in the hands and feet. See a doctor if you experience these symptoms”.

Q10. Do the current definitions and compositional and labelling requirements in the Code relating to sports foods pose any difficulties in compliance or enforcement? If yes, please provide reasons why and examples.

The essential compositional requirements of FSSFs, that they must not contain, in a *one-day quantity, more than: (a) 70 mmol sodium; or (b) 95 mmol potassium, do not generally pose difficulties in compliance or stifle innovation. However, it is essential, noting the impracticalities, restraints, and costs consequences reported in relation to the current regulation of fortified foods, as highlighted in our response to Q2, that these compositional requirements in relation to the FSSF category should not be made more any restrictive in revised iterations. It seems reasonable that these compositional requirements should be reframed in the context of the contemplated risk-based classification of nutritive substances, which we support. The essential compositional requirement should only be that the food or beverage is (a) specifically formulated to support particular nutritional or performance outcomes and (b) that it contains added nutritive substances. Maximum nutritive substance volumes or nutritional content should still be applied but should not form part of the definition or essential compositional requirements.

The current requirements to disclose in the NIP the volume of nutritive substances added does not generally create a compliance burden, and should be retained. However, careful consideration should be given to pack size and available space (as well as font size, specific wording, and specific placement requirements) to ensure that compliance does not become more impractical as the FSSF standard is revised.

D. Labelling

Q14. Are the existing labelling requirements in the Code for sports foods appropriate for managing potential risks to public health and safety? Please provide details on why or why not.

Please see our responses at Q8 and Q10 regarding declarations and warnings, sources of consumer confusion, and potential means of achieving greater clarity in messaging to consumers around risk. We consider that improvements could be made in this aspect of the regulations without substantially increasing the complexity or cost of compliance for suppliers.

Q15. What are your views on the relevance to sports foods of the existing warning statement and advisory statements? Please provide reasons for your view.

We consider that the existing required warning and advisory statements are not well adapted to informing consumers about the actual risks relevant to them and to the product being consumed. It is not correct that all FSSFs utilising currently permitted nutritive substances are inherently unsafe for consumption by children or pregnant women. Our research understanding is that the required inclusion of this warning on FSSF labels can be unduly off-putting to consumers and act as a deterrent to suppliers looking to use the FSSF category as a platform for safe but innovative new product development. More importantly, the application of this general warning to all FSSF products obscures important messaging around the risks of specific substances, or volumes or modes of consumption of those substances, and may result in a general desensitisation of consumers to warnings on food labels.

This compositional risk-based approach could appropriately be reflected in and result in not only more effective maximum volume limits but more effectively tailored declarations and warnings. Products incorporating only low-risk nutritive substances should not be required to bear warnings of any kind. The generalised warnings currently applicable to FSSFs, “Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision” would logically not apply. Instead, the direction to use under supervision might be a warning best reserved for products containing high and medium risk substances.

Ideally, to effectively inform consumers about risk, warnings should be specific to risks arising from the particular substances added to a product where this is practical and appropriate to the risk level. For products containing high risks substances, suppliers could be required to label their products with a warning explaining the specific effect of consumption above recommended limits or inconsistent with use directions. This can be integrated with disclosure regarding maximum safe quantities or unsafe combinations of substances. An example of a tailored warning might be, e.g. “consumption of Vitamin b6 above Max Safe Daily Quantity may cause weakness, numbness, and/or pain in the hands and feet. See a doctor if you experience these symptoms”.

Products incorporating medium-risk ingredients might attract a general warning regarding medical supervision or caution around excessive consumption (which might be triggered by the presence of those substances or the presence of those substances above a threshold amount).

Classification based on risk and the identification of specific high or medium risk substances means a greater capacity for suppliers to apply tailored warnings (or elect not to use that substance if the warning is undesirable), reducing the barrier to innovation as identified above.

The current required advisory statements:

a) a statement to the effect that the food is not a sole source of nutrition and should be consumed in conjunction with a nutritious diet; and

b) a statement to the effect that the food should be used in conjunction with an appropriate physical training or exercise program,

do not, in our opinion, provide useful information to a consumer.

Firstly, FSSFs, and any potential replacing formulated functional food category, are clearly not intended as meal replacements or a sole source of nutrition, unlike a Formulated Meal Replacement. This message is implicit and understood by consumers in relation to all food products, unless that product represents itself as a complete source of nutrition. Statements on complimentary medicine labels to the effect that supplements are not a complete source of nutrition may be beneficial to consumers in that context because those products are not capable of sustaining life if consumed in isolation. However, FSSFs should generally be of greater or broader nutritional value than complimentary medicines and are consumed as food, not a replacement for food.

Secondly, all foods should be consumed in conjunction with appropriate exercise for health and wellbeing. This statement is not necessary for or effective at managing any health or safety risk arising from consumption. The statement does not even assist consumers in distinguishing FSSFs from other food products. The remaining risk is only that consumers may consider that a product does not deliver on the promise of support for desired performance or nutritional outcomes, which is a civil legal risk that is most appropriately managed at the discretion of the individual supplier as all other risks of this kind are.

It may, instead, be appropriate to require FSSFs or functional foods to include on label (a) a statement that nutritive substances have been added and (b) statements as to the purpose for which those nutritive substances have been added (the function(s) the product has been formulated to support). This would, however, likely equate to making health claims regarding those nutritive substances, which would require clear permissions to make health claims about nutritive substances used in FSSFs.

Q16. Please discuss whether you think the existing labelling requirements for sports foods enable consumers to make informed choices. Please provide reasons for your view.

Please see our responses at Q5, Q8, and Q15.

Q19. To inform the scope of the second consultation paper, do you have any views on how Standard 1.2.7 – Nutrition, health and related claims could apply to sports foods?

The lack of clarity and consistency in relation to claims permissions for FSSFs is a factor that currently unduly restricts innovation and is not well adapted to a genuine consumer-protective purpose.

On a preliminary basis, we believe consideration of the following key points in framing claims permissions for a category of functional food would be beneficial to suppliers and consumers:

1. It remains necessary and beneficial for consumers that suppliers should be able to make nutrition content claims in connection with both 'naturally occurring' and added nutritive substances because consumers are making their purchasing decisions in this category on the basis of nutritional content.

2. It remains appropriate that there should be minimum content requirements for making claims about the presence of vitamins and minerals (and perhaps other nutritive substances) outside the NIP and ingredients list, but how should these levels be determined (and is there any reason why levels should be different for different product categories)?

3. Terminology regarding nutrition content claims should be consistent across all product categories. "Source of" and "good source of" have a high level of recognition amongst consumers and should be adopted universally.

4. There is no safety-based justification for prohibiting the making of health claims in connection with functional foods. Consumers are seeking out these products and the specific nutritive substances in them to support the consumer in achieving specific health and performance goals. The consumer must therefore already have at least a baseline understanding of perceived health benefits associated with those substances. Providing clarity on evidenced benefits via use of specifically permitted health claims is not only logical and necessary to the product fulfilling its special purpose but may also serve a consumer-protective purpose in combatting misinformation. Permissions should not, however, be limited to (added) nutritive substances only, as the consumer is concerned with the overall health effect of consumption of the functional food or beverage, and this includes nutrients that are naturally occurring in the food.

5. Because this category specifically captures foods specially formulated to support people achieving particular nutrition, health, and performance goals, it is implicit and understood by consumers that the product is not a sole source of nutrition. The category remains a special purpose food category, and therefore it remains appropriate that these foods should not be required to meet the NPSC, as set out at S 1.2.7-18(4).