9th March 2023

Food Standards Australia New Zealand
PO Box 5423
Kingston ACT 2604
Email: submissions@foodstandards.gov.au

To whom it may concern

Submission: P1010 – Formulated Supplementary Sports Foods

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? A recent investigation from the Western Australian Institute of Sport (Waller et al. 2019) confirms supplement use remains high amongst elite athletes, with approximately 90% of athletes surveyed acknowledging supplement use in the prior 12 months. Furthermore, supplement stacking was also common, with more than four supplements being used during that time period. The most common supplements used included sports drinks i.e., electrolyte drinks (70%), caffeine (48%), protein powders (42%) and sports bars (42%). Similar practices have been noted amongst fitness centre members internationally (Mettler et al 2020).

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? The current definitions relevant to Standard 2.9.4 are in general fit for purpose. The exception may be for 'used as a nutritive substance', given the broad spectrum of substances this could relate to. Indeed, it may be these substances that could be the most concerning. As an example, there is an increasing prevalence of FSSF being fortified with botanical ingredients and their reported adverse effects (Colombo et al 2020). Is there a means of more clearly defining what is a nutritive substance, and as such, what can be included to a food?

Q3. For industry and regulators, how should proprietary blends or stacks best be regulated and why? Consideration should be given to mandating the amounts of specific substances that are included in a FSSF, to facilitate enabling consumers to make informed decisions. As such, the concept of a proprietary blend should be legislated against. A classic example would be pre-workout supplements originating from overseas, which do not provide details on the caffeine content per serve. For consumers who consume (individual) high caffeine supplements or stack several caffeine products (Paisley 2015), there may be a moderate risk, as confirmed by individual case studies (Harris et al. 2017, Bridwell et al 2020) and case summaries (de Jonge et al 2023) reported in the literature. Identifying a solution to supplement stacking is challenged. Mandating maximal amounts of key substances (like the proposal proposed by FSANZ with caffeine) will certainly help but ultimately this will need to be matched with consumer education, if dangerous practices are to cease.

Q4. For all, should the Code retain the existing definitions in Standard 2.9.4? If so, why and if not, why not? Consideration should be given to the definition of a **nutritive substance**, given it is somewhat open ended. Instead, is there an option for a clearly defined list of substances that fulfill this definition. To maintain currency of the definition, could an opportunity be made available (say annually) for industry, and other interested parties, to submit an application for new substances to be considered nutritive substance?

As suggested by FSANZ, a change to the term 'Sports People' is likely necessary, given recreationally active individuals may benefit just as much from specific FSSF. Indeed, given physical adaptations facilitated by training result in adaptations resembling those of supplement use, it could be argued non-elite athlete may benefit even more from specific supplement use. Would a term like 'physically active individuals' or 'physically active individuals and athletes' be appropriate?

Should consideration be given to changing the name of **FSSF to simply 'formulated sports supplements'** given many of these products do not resemble food in any form.

Current 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)? Could the template created by the AIS Supplement Framework be used here? As an example…

Classification	**Risk**	**Labelling requirement**
Group A supplement		
Sports Food	Low	Nil
Medical Supplements	Medium	In accordance with current requirements
Performance Supplements	High	Only under guidance of doctor or dietitian*
Group B supplements	Medium	In accordance with current requirements

**Guidance relating to caffeine in accordance with Proposal 1056. Perhaps same concept could be applied to other performance supplements?*

Q6. Is there any evidence that current practice in relation to analogues and derivatives pose a health concern or risk? If you consider that there is a health concern or risk, please provide relevant details and data, where available. Recent research on sports supplements (from the USA) confirm the presence of a number of banned stimulants including synonyms of previously banned substances (Cohen et al 2021). While these products were sourced from the USA, it is likely similar products are available on the Australian market. Many of these substances have never been approved for use in humans. It is unknown what impact recent regulatory changes proposed by TGA would have on the availability of such products in Australia.

How would the caffeine and other methylxanthines present in guarana be considered in FSSFs?

Q7. Is there any evidence in current research in relation to known analogues and derivates that pose a health concern or risk? If you consider that there is a health concern or risk, please provide relevant details and data, where available. As per prior question response.

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? There are likely only two, concurrent options available to address this… 1. Moderating single does amounts, as per Proposal 1056 relating to caffeine, complemented by 2. An education piece targeted at key stakeholders on the health implications of intake above the recognised one-day quantity.

Q9. To what extent are vulnerable consumers regularly consuming sports foods? Please provide evidence. Athletes in general are a group vulnerable to the emotive marketing of supplement companies. Indeed, supplement use is common practice amongst athletes domestically (Shaw et al 2016, Waller et al 2019) and internationally (Daher et al 2022). Athletes may be particularly vulnerable to supplement information from readily available sources, including the internet, teammates, family and coaches (Barrack et al 2020).

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 current definitions relevant to Standard 2.9.4 are in general fit for purpose. The exception may be for 'used as a nutritive substance', given the broad spectrum of substances this could relate to. Indeed, it may be these substances that could be the most concerning. As an example, there is an increasing prevalence of FSSF being fortified with botanical ingredients and their reported adverse effects (Colombo et al 2020). Is there a means of more clearly defining what is a nutritive substance, and as such, what can be included to a food?

The use of proprietary blends on supplement labelling should be outlawed, so as to enable consumers to make informed decisions relating to specific substance ingestion.

Electrolyte Drinks

Q11. If the existing requirements for electrolyte drinks were transferred to a special purpose food standard (i.e. under Standard 2.9.4), what impacts (positive or negative) might this have on industry, regulators and/or consumers? It is logical for electrolyte drinks to come under Standard 2.9.4. Indeed, sports drinks come under Group A Sports Foods within the AIS Supplement Framework. However, consideration should be given to renaming electrolyte drinks to 'sports drinks', given the potential confusion with 'electrolyte supplements' within the AIS Framework, which are better aligned with products such as oral rehydration solutions.

Electrolyte drinks comply directly with the definition of a sports food i.e., 'specifically formulated to assist sports people in achieving nutrition or performance goals'. Reclassifying may afford an opportunity to better prescribe intake aligned with best practice. Furthermore, classification under 2.9.4 may better enable evolution of this product range into the future, especially as it relates to the inclusion of other nutritive substances, which may assist in achieving specific nutrient intake goals before, during and/ or after exercise.

Q12. If electrolyte drinks were to remain a general purpose food (i.e. under Standard 2.6.2) what impacts (positive or negative) would this have on industry, regulators and/or consumers? There is unlikely to be a significant impact on industry by keeping electrolyte drinks in Standard 2.6.2. The only issue that might emerge is a limit on the evolution of the formulation of electrolyte drinks if they remain within Standard 2.6.2.

Q13. How would transferring electrolyte drinks to Standard 2.9.4 impact consumer messaging around their purpose and use? Please provide reasons for your view. This may afford an opportunity for cleared direction on appropriate use of electrolyte drinks, in accordance with best practice guidance.

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. There is evidence of disparity between labelling claims, including composition, and independent compositional analysis. A recent review of pre-workout supplements commercially available in Australia confirmed a caffeine content ranging from 91-387 mg per serve (Desbrow et al 2019). However, only 6 of the 15 products reviewed included details on the caffeine content, with the investigation also confirming meaningful differences in the actual caffeine content relative to that specified on the label. It is unclear if current regulations would remove such risk from these high caffeine products.

The above also supports claims about enabling 'proprietary blends' to not disclose the amounts of specific substances.

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. It is unknown if current statements (e.g., the food is not a sole source of nutrition and should be consumed in conjunction with a nutritious diet; should only be used under medical or dietetic supervision) influence consumer behaviours. Perhaps stronger, more targeted statements could be considered for vulnerable populations, like children/ adolescents, pregnant individuals? Alternatively, could consideration be given to explicit guidance on caffeine dosages that may be problematic and/ or description of symptoms in response to excessive consumption?

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. Labelling requirements should enable consumers to make more informed choices. However, understanding of what is best practice relating to sports food prescription has evolved significantly in recent years. Guidelines should be updated to reflect this.

Q17. What are your views on the usefulness of the labelling statements in Division 3 for particular sports foods (high carbohydrate supplement, protein energy supplement, energy supplement)? Please provide reasons for your view. The classification of some sports foods is confusing. As an example, the definition of an energy supplement is confusing. The 'optional statements' could be adjusted to better reflect current best practice. For example, there is little research supporting the use of protein energy supplements during exercise. Indeed, consumption of protein during exercise is associated with increased gastro-intestinal tract distress (Pfeiffer et al 2012).

Would a high protein supplement also need to be defined here? Within the AIS Supplement Framework, these are termed 'Isolated protein Supplements'.

What about higher electrolyte supplements, should they be considered? Here we are not talking specifically to oral rehydration solutions, but products like Nuun.

Q18. Have you identified issues on any other labelling aspects specific to sports foods? Please provide detail. No.

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? It would seem logical that Standard 1.2.7 should apply to sports foods. Is there an opportunity to integrate into Standard 1.2.7 a section specifically relating to sports performance claims?

References

Barrack et al. An investigation of habitual dietary supplement use among 557 NCAA Division I athletes. Journal of the American College of Nutrition. 39:619-27, 2020.

Bridwell et al. Chest pain from supplement use in an active-duty soldier: A case study. Military Medicine. 185:e1857-e1859, 2020.

Cohen et al. Nine prohibited stimulants found in sports & weight loss supplements: deterenol, phenpromethamine (Vonedrine), oxilofrine, octodrine, betamethylphenylethylamine (BMPEA), 1,3-dimethylamylamine (1,3-DMAA), 1,4-dimethylamylamine (1,4-DMAA), 1,3-dimethylbutylamine (1,3-DMBA) and higenamine. Clinical Toxicology. 59:975-81, 2021.

Colombo et al. Adverse effects of food supplements containing botanical ingredients. Journal of Functional Foods. 72:103990, 2020.

Daher et al. Prevalence of dietary supplement use among athletes worldwide: A scoping review. Nutrients. 14:4109, 2022.

de Jonge et al. Review of case reports on adverse events related to pre-workout supplements containing synephrine. Cardiovascular Toxicology. 23:1-9, 2023.

Desbrow et al. Caffeine content of pre-workout supplements commonly used by Australian consumers. Drug Testing and Analysis. 11:523-529, 2019.

Harris et al. Hemorrhagic stroke in a young healthy male following use of pre-workout supplement animal rage XL. Military Medicine. 182:e2030-e2033, 2017.

Mettler et al. High prevalence of supplement intake with a concomitant low information quality among Swiss fitness center users. Nutrients. 12:2595, 2020.

Paisley. Nutritional and sports supplement use among deployed US army soldiers in a remote, austere combat outpost in Eastern Afghanistan. Military Medicine 180:391-401, 2015.

Pfeiffer er al. Nutritional intake and gastrointestinal problems during competitive endurance events. Medicine and Science in Sports and Exercise. 44:344-51, 2012.

Shaw et al. Supplement use of elite Australian Swimmers. International Journal of Sport Nutrition and Exercise Metabolism. 26:249 -58, 2016.

Waller et al. Supplement use & behaviours of athletes affiliated with an Australian state-based sports institute. International Journal of Sport Nutrition and Exercise Metabolism. 29:518-25, 2019.