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Dear FSANZ,

The TGA would like to submit the responses outlined below for consideration as part of the consultation into P1010 - Formulated Supplementary Sports Foods Stage 2 Review. Please note we have not responded to all questions, only the ones relevant/appropriate for us to comment on. Once there are proposed changes to the legislation available for comment, the TGA would welcome the opportunity to provide more specific feedback.

The below submission was Director/EL2 cleared.

Question 2) 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 TGA is responsible for the regulation of therapeutic goods within Australia, as well as for performing Food-Medicine Interface (FMI) Assessments as agreed with food regulators. These FMI Assessments are used to determine which regulatory framework products are regulated under, food or therapeutic goods. Under the *Therapeutic Goods Act 1989,* unless declared to be a therapeutic good, a food is excluded from being a therapeutic good when it is a product;

1. for which there is a standard (within the meaning of subsection 4(1) of the Food Standards Australia New Zealand Act 1991); or
2. which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented;

In relation to item 1 in the above list, the definitions within the food standards are the most consequential and important. If the definitions within a standard are very broad or open, this can cause issues for appropriately and accurately determining whether the product is a '*good for which there is a standard*'. It should be noted that non-compliance with other aspects of a standard is not the same as there not being a standard for the goods.

Question 3) For industry and regulators, how should proprietary blends or stacks best be regulated and why?

From both a safety and a regulatory perspective, products containing proprietary blends with restricted ingredients or ingredients that are not recommended above certain limit (e.g. caffeine, synephrine/oxedrine) should be required to disclose the quantities of such substances on their label together with advisory statements regarding maximum safe intake of those substances per day. This is to ensure that consumers can be aware of the substances they are consuming and do not exceed the safety limits if consuming additional products containing the same substances.

Further, rules should be clarified to prevent (or make clearer it is not acceptable) for manufacturers to design multiple products just under maximum levels of ingredients (or restricted substances) and then recommend them to be consumed together. This is a clear breach of the intention of these upper limits.

Question 4) For all, should the Code retain the existing definitions in Standard 2.9.4? If so, why and if not, why not?

The current definition of formulated supplementary sports food within Standard 2.9.4 is very broad (pasted below for reference)

> ***formulated supplementary sports food*** *means a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals.*

This could capture a broad range of products, however it appears the intention of the standard (particularly when read in full) may have been that the 'or' should in fact be an 'and'. i.e. (see highlighted change)

> ***formulated supplementary sports food*** *means a product that is specifically formulated to assist sports people in achieving specific nutritional and performance goals.*

As this would require products to actually provide nutrition and not just be non-food/non-nutritional ingredients for performance goals without nutrition (i.e., therapeutic use).
Also, '*sports people*', in a practical sense, does not have a clear meaning. It could include people that exercises at all levels of intensity, which does not appear to be the intention of the standard. Lastly, to avoid confusion and non-compliance with standard 1.2.7, the term '*performance goals*' should be more specific in relation to supporting/maintaining performance goals.

Question 5) 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)?

Typically for therapeutic goods, medium-high risk substances that are permitted for use are required to show (among other aspects) a favourable risk-benefit profile, i.e. that the benefits outweigh the risks. Food is intended to be for a nutritional purpose. With that in mind, in our view we do not believe that there is an instance where medium-high risk foods would, particularly in relation to sports supplements, produce a favourable risk-benefit in relation to nutrition. If the benefit is non-nutritional and performance-based improvement (outside of nutrition), then it is more likely to be for a therapeutic use than for foods.

Question 8) 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?

Please see answer to question 3. Briefly, a combination of mandatory disclosure on labels, accompanied by advisory statements (as both are needed to achieve the intended outcome). Requirements should also be introduced (or clarified if existing) to prevent the development and advertising of 'stacks' of products designed to facilitate dosing in excess of permitted limits of substances. Potentially one option is labelling requirements for limits from all sources.

Question 11) 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?

As discussed above, the definitions are the most important section of a standard for determining '*goods for which there is a standard*'. In that sense, the TGA's primary concern would be how the move would affect the definitions and welcome the opportunity to provide further feedback if the movement is done and definitions updated. Compositional requirements are not necessarily an applicable consideration from an FMI perspective.

Question 18) Have you identified issues on any other labelling aspects specific to sports foods? Please provide detail.

As outlined in response to question 3, we believe it would be best practice regulation to require both, proprietary blends to disclose quantities of potentially restricted ingredients (e.g. caffeine, synephrine/oxedrine) to ensure they are not exceeding these limits.

Question 19) 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.

As per section 7 of Standard 2.9.4 (below), it appears on an initial read that Standard 1.2.7 would not and should not apply to sports foods.

> ***2.9.4—7 Prohibited representations***
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> *Unless specific permission is given in Division 3, the label on a package of formulated supplementary sports food must not include an express or implied representation that relates any property or proposed use of the food to enhanced athletic performance or beneficial physiological effects.*

Any attempt to apply Standard 1.2.7 and subsequently Schedule 4 – Nutrition, health and related claims to Standard 2.9.4 is likely to expand the already overly broad range of the standard. It may also result in additional grey areas

and reduce existing clarity the standard currently provides from a Food-Medicine Interface perspective, particularly if the definition is not changed as suggested above (Q4) to require nutritional content.

If any of the above responses are unclear or you would like further clarification of the views/information raised, please let me know.

Kind regards,

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The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.