Dynamic | Solutions Driven | Innovation

P1010 – Formulated Supplementary Sports Foods

Thursday, 9 March 2023

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

Healthcare Product Specialists Submission: P1010 – Formulated Supplementary Sports Foods

Dear Food Standards Australia New Zealand Submissions Branch,

Healthcare Product Specialists (HPS) welcomes the opportunity to provide comment and feedback on the Food Standards Australia New Zealand (FSANZ) call for submission to proposal P1010 – Formulated Supplementary Sports Foods. HPS are a product development and regulatory agency within the functional food industry, working with industry bodies, manufacturers, suppliers and retailers, supporting ongoing development and innovation of food products such as supplementary foods and formulated supplementary sports within the health sector. HPS has many years' of experience working within the Food Standard Code and are fully abreast of the requirements of Standard 2.9.4 on Formulated Supplementary Sports Foods.

We understand the proposal to review all aspects of Standard 2.9.4 Formulated Supplementary Sports Foods to protect public safety. We believe it is essential that we share our comments and concerns, given the potential ramifications of the implementation of these changes to our clients. We hope that the information contained is appreciated.

[redacted]

P1010 – Formulated Supplementary Sports Foods

Response to proposed questions:

Comments	HPS specific comments
Q3. For industry and regulators, how should proprietary blends or stacks best be regulated and why?	HPS recommends a cross functional approach is needed here. Including education for consumers who are seen as vulnerable to dietary inadequacy, as well as the addition of information on the label (within the Nutrition Information Panel or label statements) for those ingredients recognised as potentially 'unsafe', if there is substantial risk that the Upper Intake Limit (UL) will be exceeded in a total daily dose (total serves per day). Regarding proprietary ingredients, it is HPS's understanding that proprietary ingredients should be regulated like any other compound ingredient as required under standard 1.2.4 Information requirements – statement of ingredients and Standard 1.2.8 Nutrition information requirements. As stated in section 4.2.2 of P1010, if '*many of these products also include 'proprietary blends' where the blend is listed in the ingredients list and as a 'blend' included in the nutrition information panel (NIP), but do not separate out the amounts of each individual ingredient in the NIP*', it is understood that example like this would be seen as a noncompliance under Standard 1.2.8 at a minimum. HPS requests FSANZ to provide clear guidance on how proprietary ingredients are to be labelled (and regulated) to enable industry an opportunity to comply with the legislation in a safe and appropriate manner. Additionally, we also request that FSANZ provide clarity surrounding which ingredients contain inherent safety risk, and risk of consumers exceeding the UL if a consumer is takes multiple products in one day and ingredients are 'stacked'. For example, if a particular ingredient such as L-carnitine is used in a product at 1g per serve, the quantity (microgram, mg, g) of L-carnitine is required to be included within the nutrition information panel advising consumers of the level of this ingredient in the product. Or a label statement is triggered such as; 'Do not consumer more than 2g of L-carnitine per day from all sources' (or words to that effect).
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)?	High risk products should be kept at therapeutic goods, monitored and regulated by the TGA under the Therapeutic Goods Act, as noted in section 2.2.8.1 of P1010. As noted, the TGA's interactive Food Medicine Interface Guidance Tool offers businesses an opportunity to determine if their product is a food or a therapeutic good. HPS highlight that the introduction of a tiered approach, high, medium, low risk product has the potential to cause confusion for consumers as well as regulators. There would be significant risk that 'high risk FSSF products' could be confused for being therapeutic goods, placing an unnecessary burden on businesses. Further, if additional regulatory framework is added to rectify noncompliant FSSF products, will the current enforcement be adequately funded to adequate enactment at the local level.

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.	HPS supports the notion to permit additional forms of vitamins and minerals (analogues or derivatives already approved for use within the restraints under Schedule 29; i.e. magnesium gluconate is not currently permitted for use in FSSF however this is approved for use in other areas of the food code) for use in FSSF. This would enable further compliance by industries retailers while also promoting further opportunity for innovation and development within this sector.
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?	The definition of an electrolyte drink per Standard 2.6.2 is: ***electrolyte drink*** *means a drink formulated for the rapid replacement of fluid, carbohydrate and electrolytes during or after 60 minutes or more of sustained strenuous physical activity.* This definition in isolation, as noted above appears to fit within the regulatory framework of Standard 2.9.4, FSSF, specifically the text underlined supports the motion to move electrolyte drinks into a special purpose food standard. However, it is worth noting that, electrolyte drinks are not only used for the purposes of replacing fluids '*after physical activity*' as defined by the Code. Thus, HPS suggests that the definition for 'electrolyte drinks' be revised to include all intended uses, during dehydration. HPS support the notion to separate 'electrolyte drinks' from Standard 2.6.2 Non-alcoholic beverages and brewed soft drinks, however the addition of electrolyte drinks into Standard 2.9.4 does not provide industry with clarity surrounding the regulatory framework of electrolyte drinks, as this category contains very specific regulatory requirements outside the regulatory framework of Standard 2.9.4. Further, the legislative framework surrounding the regulatory requirements for electrolyte drinks (Standard 2.6.2 – Division) is currently are out of touch with today's consumer, the legislative requirements do not account for consumers who wish to consume less sugar, when rapidly replacing fluids.
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.	As noted in response to Q11, HPS do not support the notion to move electrolyte drinks into Standard 2.9.4 as FSSF, due to the regulatory differences between electrolyte drinks and FSSF. In our view, the inclusion of electrolyte drinks into Standard 2.9.4 could further confuse industry, this could have a flow on effect to consumers. HPS do support the notion to move electrolyte drinks under Part 2.9 Special Purpose Foods, however HPS suggests Electrolyte Drinks have their own unique standard under Part 2.9 of the Code, outside the regulatory framework of Standard 2.9.4 primarily due to the different regulatory requirements placed on each category of food product. This approach would provide clarity to both industry and consumers and supports FSANZ objective of protecting consumer safety.

P1010 – Formulated Supplementary Sports Foods

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.	In HPS's view, labelling requirements in Standard 2.9.4 could be improved, as noted below: *Standard 2.9.4—7 Prohibited representations* *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.* The use of the prohibited representation (2.9.4-7) is unclear in its intended use, the industry seeks clarification around its intended use and proposal. In HPS's view the prohibited representation does not directly apply to the Food Standard code within the context of Standard 1.2.7 and Schedule 4 Nutrition, health and related claims. The industry is unclear if the prohibited representation applies to claims that are deemed therapeutic in nature or applies to those health claims reflected in Standard 1.2.7 and Schedule 4. HPS requests FSZNZ to provide further clarification surrounding the intent and use of this prohibited representation, by either directly linking to the intended prohibited area of the FSC or providing clarity about its intended use enabling the industry body to continue to strive for compliant labelling and marketing of sports foods in this sector. HPS suggests removing the 'one-day quantity' for formulated supplementary sports foods. As this restriction is not placed on any other food category within the Code. Further, as stated within section 4.2 of the proposal, standard 2.9.4 includes upper levels of nutritive substances, this should be applied on a per serve basis rather than applied per day. Please see response to Q3, HPS support the need to protect consumer safety through a cross functional approach, promoting consumer education and introducing UIL 'warning statements' on pack.
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.	In HPS's view the compositional requirements for particular sports foods defined by Division 3 are out of touch with 'today's' sports food industry. Formulating products to fits within a restraint of Standard 2.9.4 – Division 3 is difficult. For example, today's consumer seeks high protein FSSF, a maximum protein content (max - 30% protein) limits innovation and is at juxtaposition with the market needs. HPS suggest removing the maximum protein requirement for 'protein energy supplement'. Further, in our view high carbohydrate supplement and energy supplement compositional requirements limit innovation and opportunity and product development in the FSSF space. HPS question if Standard 2.9.4 - Division 3 retains relevance in today's FSSF market.

P1010 – Formulated Supplementary Sports Foods

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 regulatory framework of Standard 2.9.4 does not directly permit (or prohibit) health claims on FSSF. As noted under Q14 above, it is unclear on whether the 'restricted representation defined in 2.9.4 - 7' applies to 'health claims' generally, therapeutic indications (as defined by the Therapeutic Goods Act; Therapeutic Goods) or if Standard 2.9.4 only permits health claims mentioned under Standard 2.9.4 - Division 3 (High carbohydrate supplement, protein energy supplement, energy supplement). Further, section 6.1.5 of P1010 discusses "*Nutrition content and health claims about sports foods are regulated by Standard 1.2.7 and Standard 2.9.4.... Standard 1.2.7 does not apply to claims expressly permitted elsewhere in the Code (refer to paragraph 1.2.7—6(a)), such as those permitted for sports foods in Division 3 of Standard 2.9.4. Claims that are therapeutic in nature are not permitted (section 1.2.7—8).*" While Standard 1.2.7 and Schedule 4 permits health claims on 'foods', the interpretation and application of Standard 2.9.4 – 7 is confusing, in our view this places business at risk of non-compliant marketing of FSSF which in turn could inadvertently risk consumer safety. The industry seeks clarity surrounding the intent and use of health and nutrition claim on FSSF.

Thank you for your consideration.

[redacted]

[redacted]

[redacted]