New Zealand Food Safety
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Tēnā koe,

Proposal P1010 – Formulated Supplementary Sports Foods (Consultation Paper One)

Thank you for the opportunity to comment on this Proposal.

New Zealand Food Safety (NZFS) welcomes the recent work by FSANZ on the review of Formulated Supplementary Sports Foods (FSSF) under Proposal P1010. It is well acknowledged that Standard 2.9.4 is no longer fit-for-purpose and that a comprehensive review of the standard is needed. The Standard needs to be updated to ensure the safe and appropriate use of sports foods by consumers, to better reflect the diversity and composition of sports food products, to provide regulatory certainty for industry and regulators, and to support future innovation in this product sector.

NZFS has the following general comments to make in response to this initial consultation paper. We look forward to providing more specific comments and direction as P1010 progresses to help shape the regulatory framework and requirements for sports foods.

Current regulatory environment

Information on relevant New Zealand regulations is provided in Appendix One. This could supplement the information provided in section 2.2 of the P1010 Consultation Paper.

Purpose of Standard 2.9.4

In the review of Standard 2.9.4, we see value in first clearly articulating why FSSF are considered a special purpose food, why they should be classified in this way, and the definitional boundary with a general purpose food. Having clarity about the target population subgroup and purpose for these products should then assist to define the product category and to determine the scope of products to be regulated under this category.

In principle, we support the use of a risk proportionate (tiered) approach once it is clearer how this could be applied and the intersect with other regulatory product categories.

Definitions

FSANZ has identified two definitions for review under P1010 – the definitions for 'formulated supplementary sports foods' and 'one-day quantity'.

Formulated supplementary sports foods – we consider a product category definition that identifies a defined population subgroup and the purpose of the food is essential to provide regulatory

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certainty. A well-constructed product category definition is necessary to clearly differentiate sports foods from other regulatory product categories, and so it is clear to industry and regulators which regulatory requirements a food must comply with.

One-day quantity – we are not aware of any issues with the operation of this definition which is used to indirectly provide a compositional limit for permitted substances in sports foods. However, we note the issue raised by FSANZ about consumers 'stacking' products and potentially exceeding maximum recommended intakes for certain substances. As one-day quantity relates to the individual product alone, it is appropriate to consider if other risk management tools could be used to alert consumers to the risk of exceeding intakes of certain substances that may be added to multiple foods consumed in a day. Tools that could be considered include: advisory statements specific to a high-risk substance and the respective upper level of intake that could be used in conjunction with nutritional information provided on product labels, or digital linking to off-label web-based information. While it is appropriate that requirements should protect consumers, there are limits to those requirements if consumers intentionally choose to consume products in a particular manner (e.g. stacking).

We also consider the definitions for *'high carbohydrate supplement', 'protein energy supplement', and 'energy supplement'* (under division 3) will need to be reviewed, depending on the revised regulatory framework adopted for sports foods and if these product categories are still relevant.

Composition / framework

Permitted substances

NZFS supports continued use of the regulatory framework that prohibits the addition of substances to sports foods unless expressly permitted in the Code. This approach best protects public health and safety, and ensures best available scientific evidence is reviewed as part of a pre-market safety assessment before any new substance is permitted for use in sports foods.

In updating the regulations for sports foods under P1010, we recommend FSANZ undertakes pre-market safety assessments for a range of new substances (and associated permitted forms) that achieve a specific sporting purpose, to update the current list of permitted substances in FSSF.

We note that current compositional provisions in Standard 2.9.4 relate to substances used as a nutritive substance, which are defined to achieve a nutritional purpose when added to a food. As the purpose of sports foods is broader than for a nutritional purpose alone and may include assisting sports people in achieving specific performance goals, we consider that future compositional provisions should reflect the wider purpose for substances added to these foods.

Permitted forms

In relation to *questions 6 and 7*, we note the current approach which prohibits the use of any analogues or derivatives of substances that are listed in the Code unless expressly permitted, and express permission may be sought via an application to amend the Code. NZFS supports maintaining this requirement. The pre-market safety assessment protects public health and safety by ensuring that any analogues or derivatives are assessed on a case-by-case basis, using up-to-date evidence. This process future-proofs Standard 2.9.4, as analogues and derivatives of substances that are yet to be developed must be individually assessed for safety.

Compliance and enforcement issues

In relation to *question 10* about whether current definitions and compositional and labelling requirements pose any difficulties in compliance or enforcement, below are examples of enquiries we have received from food businesses and/or enforcement issues we have encountered:

- *Whether caffeine can be added to sports foods.*

  We note that some sport food products currently regulated as supplemented foods (under the NZ SFS) are compliant with Standard 2.9.4 except for the addition of caffeine. The proposed regulatory option under P1056 to permit the addition of caffeine to FSSF should help to resolve this issue, and to transition these products to be regulated under the Code.

- *Some imported products contain higher levels of nutrients than permitted in the Code and the product labels may incorrectly identify them as dietary supplements.*

  P1010 and other work in the New Zealand regulatory space should provide regulatory clarity for food businesses on the appropriate regulatory classification and composition and labelling requirements for sports foods, as well as certainty for regulators to allow appropriate enforcement action to be taken if needed.

- *Labelling statements required in division 3 are not relevant for the product-type, for example some carbohydrate energy gels do not need to be consumed with water.*

  We request that P1010 considers the appropriateness and need for the three product categories under division 3 based on the current market, and how a future framework could remain flexible to accommodate future innovation in this product category.

- *Whether there is a list of approved nutrition content and health claims for FSSF, and use of statements on product labels outside those permitted under division 3 of Standard 2.9.4.*

  We welcome consideration under P1010 for how nutrition, health and related claims could apply to sports foods, as well as specific labelling requirements for these products.

Electrolyte drinks

Electrolyte drinks and the appropriate classification of these products in the Food Standards Code should be considered in scope for P1010. This was requested by the New Zealand Minister at FMM03.

We support including electrolyte drinks in the same standard as sports foods as they are used for the same purpose. Electrolyte drinks are a logical subset of FSSF because they are specifically formulated for rapid rehydration to sustain athletic performance when strenuously exercising for a duration of at least 60 minutes or more, which is based on robust scientific evidence. In the P1030 approval report the prescribed approved health claims for electrolyte drinks specify that this statement about exercise duration must be included in the health claim. The P1030 approval report also states that the rationale for this approach "was to reduce the potential for consumers to be misled about the benefits of electrolyte drinks and their place in the diet". While electrolyte drinks can certainly be consumed by the general population, they are not designed for the general population, but rather the hydration and performance requirements of endurance athletes. As such they should not be subject to the Health Star Rating system, as this is a system designed for the nutritional needs of the general population.

In response to *questions 11 & 12* in the consultation paper: As a regulator, we support FSANZ's statement (in the P1030 approval report) that electrolyte drinks should be appropriately portrayed "to reduce the potential for consumers to be misled about the benefits of electrolyte drinks and their place in the diet". Regulating electrolyte drinks alongside other sports foods as special purpose

foods seems the most logical way to achieve this outcome. It would also clearly demonstrate to food businesses the expected intent and positioning of these products on the market.

In response to *question 13*, we consider transferring electrolyte drinks to Standard 2.9.4 would help to clarify for consumers that electrolyte drinks are designed to meet the very specific hydration and performance needs of athletes who undertake strenuous exercise for 60 minutes or more. While it is not necessarily harmful for others to consume electrolyte drinks, the current New Zealand Eating and Activity Guidelines (which are designed for the general population, not athletes), state "Make plain water your first choice over other drinks", so to clarify the intended population group for electrolyte drink use is consistent with current dietary guidelines for the general population. In addition, as consumers receive most messaging through labelling and marketing of products, the transfer of electrolyte drinks to Standard 2.9.4 would clearly demonstrate to industry the expected intent and positioning of these products and therefore the appropriate messaging for consumers about the purpose and use of electrolyte drinks.

We also support an updated review of the evidence underpinning electrolyte drinks to ensure the requirements are in line with the latest evidence on hydration for endurance sports.

The Ministerial Policy Guideline on the intent of Part 2.9 – Special Purpose Foods (the Policy Guideline) will apply to electrolyte drinks if it becomes part of Standard 2.9.4. We note some issues in applying the Policy Guideline to electrolyte drinks (and sports foods in general). The Policy Guideline provides a very narrow scope for situations where "there is a risk of dietary inadequacy to support … physical and physiological conditions that require altered energy intake". Depending on the sport, the dietary inadequacy may not be due to an altered energy requirement, but instead may be from an altered macro-nutrient, micro-nutrient or nutritive substance requirement; or in the case of electrolyte drinks, the use of sodium for hydration purposes. The purpose of the sports food or electrolyte drink may be to enhance performance rather than to support dietary adequacy. FSANZ may wish to bring this to the Food Regulation Standing Committee for their consideration as part of their review of policy guidelines.

Labelling

We consider it too early to comment on whether existing labelling requirements in the Code for sports foods appropriately mange potential risks to public health and safety and enable consumers to make informed choices (*questions 14-16*). Labelling requirements would be best considered once the regulatory framework and compositional provisions for sports foods is further developed, with labelling used tool to manage any identified risks.

We also note that some current labelling statements required under Division 3 of Standard 2.9.4 may no longer be fit-for-purpose given product development within these categories. For example, some carbohydrate gels can be consumed without water, so a required statement to the effect that the food must be consumed with an appropriate fluid intake is not relevant for such a product.

Nutrition content and health claims / Prohibited representations

Sports nutrition is a rapidly evolving field of nutrition science. Applying Standard 1.2.7 to sports foods will help to future-proof Standard 2.9.4 and support future innovation to keep pace with this evolution. The permitted health claims in Division 3 are limited to categories that no longer reflect the diversity and composition of products, and there is no pathway to communicate more recent scientific evidence unless self-substantiated claims are permitted. In New Zealand, where we have adequately resourced the assessment and enforcement of Standard 1.2.7, we have been able to demonstrate repeatedly that the requirements of Schedule 6 can be met when food businesses hold extensive evidence to self-substantiate their food-health relationships. We do not see a compelling justification for FSSF to be treated differently to general foods in relation to health claims.

As special purpose foods, FSSF carrying health claims are not required to meet the NPSC. This is appropriate given the specialised purpose of sports foods, such as carbohydrate gels. However, it will be necessary to ensure that FSSF are clearly differentiated from general foods, so that general foods cannot be inappropriately categorised as FSSFs in order to avoid meeting the NPSC. With the proposed permissions for addition of caffeine to FSSFs, this could also create a loophole for general foods with added caffeine unless FSSFs are securely ringfenced.

Thank you for the opportunity to comment on this Proposal and please contact us if you would like to discuss any points made in this submission. We look forward to ongoing updates and dialogue with FSANZ as this proposal progresses.

Nāku noa, nā

Appendix One: New Zealand's regulatory environment

New Zealand Supplemented Food Standard

In New Zealand, "supplemented foods" are regulated by the New Zealand Food (Supplemented Food) Standard 2016 (SFS), which is a New Zealand-only standard issued under the Food Act 1981. A supplemented food is 'a product that is represented as a food, but has been modified in some way or had substances added, so that it performs a physiological role beyond simple nutritive needs.' Examples of supplemented foods include highly fortified protein bars, protein powders and beverages.

The SFS is aligned to the extent possible with the requirements of the Food Standards Code. Many of the standards in the Code apply to supplemented food, in full or in part (noting that standard 2.9.4 does not apply to supplemented food). The application of the Code to the SFS ensures that the regulatory requirements that apply to supplemented food are as similar as possible to those that apply to food in general.

Dietary Supplements Regulations 1985

In New Zealand, "dietary supplements" are regulated by the Dietary Supplements Regulations 1985, which were made pursuant to the Food Act 1981. The manufacture of dietary supplements is regulated under a number of regimes (including the Food Act 2014 and Animal Products Act 1999). Dietary supplements are not required to meet the Food Standards Code.

The regulations describe a number of requirements including, but not limited to, labelling and maximum permitted daily doses for several vitamins and minerals. In general, dietary supplements are substance(s) for oral use that are packed in a controlled dosage form (liquid, powder or tablet) and are intended to supplement the intake of that substance(s) normally derived from food. Dietary supplements cannot contain ingredients that are listed as medicines or have a stated or implied therapeutic purpose.

Therapeutics Products Bill

In New Zealand the Therapeutic Products Bill is currently progressing through Parliament. It is intended to replace the current Medicines Act 1981 and the Dietary Supplements Regulations 1985. The new Bill will provide for a comprehensive, risk-proportionate regulatory regime for therapeutic products (medicines, medical devices and natural health products including vitamin and mineral supplements) to support public health and safety.

The Bill will come into force in September 2026 (unless earlier).

The FSSF/dietary supplement/supplemented food/medicine interface

In New Zealand, sports foods/supplements could fall under the Code, the Supplemented Food Standard, the Dietary Supplements Regulations or the Medicines Act.

The appropriate regulatory category (i.e. FSSF, supplemented food, medicine or dietary supplement) for most products is relatively clear. There are some products, however, for which such determinations are more difficult. These products include innovative 'functional foods' fortified with nutraceuticals newer to market or in development.

A key objective for MPI is to ensure regulatory coherence between the multiple regulatory regimes that impact on the operations of food producers.