FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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P1010 – Formulated Supplementary Sports Foods

Consultation Paper One: Regulatory Framework for Standard 2.9.4

Executive summary

Food Standards Australia New Zealand (FSANZ) is reviewing regulatory requirements for formulated supplementary sports food (FSSF) products under Proposal P1010. Sports foods are regulated in the Australia New Zealand Food Standards Code (the Code) under Standard 2.9.4 – Formulated supplementary sports foods and Schedule 29 – Special purpose foods. Other standards also contain provisions related to definitions, calculations, labelling and nutrition and health claims. Proposal P1010 is reviewing all aspects of Standard 2.9.4.

The protection of public health and safety is a primary legislated objective for FSANZ. Sports foods must be safe for consumption and, as special purpose foods, their composition must support those vulnerable to dietary inadequacy in the context of sport performance. The purpose of this consultation paper is to gather views on how the current iteration of the standard is working for all stakeholders.

All submissions to consultation papers released as part of this Proposal will inform FSANZ's assessment and any proposed amendments to the Code. Proposal P1010 is being assessed under a Major Procedure, meaning there will be two public calls for submissions as part of FSANZ's formal assessment.

FSANZ is seeking stakeholder comment on the issues outlined in this consultation paper. Specific questions for stakeholders have been included in each section as well as a summary list in the final section of the paper.

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1 Introduction

Standard 2.9.4 – Formulated supplementary sports foods was gazetted in the Australia New Zealand Food Standards Code (the Code) in 1998 and is the only standard that was not reviewed when the joint Code came into effect in 2000-02. As a result, Standard 2.9.4 still reflects the 1990s market and product categorisation. Since then, the sports food market has grown significantly with greater diversity of products, product composition and consumers. Proposal P1010 – Review of formulated supplementary sports foods, aims to ensure regulation within the Code relating to Formulated Supplementary Sports Foods (FSSF) is clear and functions well now and considers future possible innovation.

1.1 Purpose of consultation paper

This paper continues stakeholder consultation for Proposal P1010 and discusses aspects of the regulatory framework for Standard 2.9.4, Schedule 29 and other relevant standards in the Code.

This consultation paper focuses on the framework underpinning the regulation of sports foods in Australia and New Zealand. Food Standards Australia New Zealand (FSANZ) is seeking views on various aspects of this regulation. FSANZ is also seeking views on the positioning of electrolyte drinks within the Code. Responses received to this consultation paper will be considered by FSANZ and will inform the proposed regulatory approach put forward in the 1st Call for Submissions (CFS).

The issues considered in this paper do not reflect the entirety of issues that will be considered in the Proposal P1010 review. Further information about the scope of this consultation paper is outlined below in Section 1.2.

1.2 Scope and approach

Sports foods are regulated in the Code under Standard 2.9.4 – Formulated supplementary sports foods and Schedule 29 – Special purpose foods. Other standards also contain provisions related to definitions, calculations, novel foods and labelling, nutrition and health claims. This consultation paper will gather views on most but not all aspects of Standard 2.9.4. It will also ask stakeholders to consider some preliminary questions on issues relevant to nutrition, health and related claims relating to sports foods, with the intention to direct the scope of a subsequent consultation paper (See section 6.1.8 of this consultation paper). Some issues including specifics around composition, safety, and labelling will be further considered as P1010 progresses.

The following are considered in this consultation paper:

- sports foods market overview
- definitions
- overarching compositional considerations
- labelling, including required statements and representations
- the positioning of electrolyte drinks within the Code.

FSANZ has not proposed any approaches to the regulation of sports foods in this consultation paper. Instead, we are seeking stakeholder views that will be considered in formulating options to be presented in the 1st CFS, in line with the *Food Standards Australia New Zealand Act 1991* (Cth) (FSANZ Act) objectives. Proposal P1010 is being assessed under a Major Procedure, meaning there will be two legislated public calls for submissions. This paper is a non-statutory, additional consultation.

2 Background

2.1 History

Proposal P1010 was formally prepared following a request from the then Ministerial Forum on Food Regulation (now the Food Ministers' Meeting) in October 2018. This request followed a roundtable on sports supplements convened in July 2018 by the Australian Government Department of Health on behalf of the Food Regulation Standing Committee (FRSC) with a view to modernise Standard 2.9.4.

Following this, a series of actions were implemented across government, including work by the Therapeutics Goods Administration (TGA) on a Section 7 declaration (see section 2.2.8.1 of this consultation paper) and the provision of risk assessment advice from FSANZ to the then Department of Agriculture, Water and the Environment (now Department of Agriculture, Fisheries and Forestry (DAFF)), on certain ingredients used in sports foods. In 2019, FSANZ completed a comprehensive analysis of the sports food environment in Australia and New Zealand, which identified issues relating to regulatory requirements, public health and safety, consumer demand, product composition and industry innovation.

FSANZ also held a Call for Data in 2021. The Call for Data facilitated early engagement with key industry stakeholders and professional associations, with FSANZ receiving 11 detailed contributions of technical, toxicological and nutritional data. Further information on the Call for Data can be found in Section 4.3 of this consultation paper.

This paper continues stakeholder engagement for P1010 and together with the Call for Data, will inform FSANZ's assessment. Finally, the following FSANZ proposals are of relevance to Proposal P1010:

- Proposal P1056: Caffeine Review - FSANZ is undertaking a full assessment of the prohibition recommended in Proposal P1054 to decide whether to confirm, reject or amend the approved variation to prohibit the retail sale of pure and highly concentrated caffeine food products. Decisions made under P1056 will influence how the P1010 review considers the use of caffeine in sports foods.
- Proposal P1030: Electrolyte Drinks - This was a review of the composition and labelling requirements of electrolyte drinks. The application of health claims to sports foods was originally included in Proposal P1030 as well as consideration of whether electrolyte drinks should be transferred to Standard 2.9.4. With the raising of the broader sports foods review under Proposal P1010, the scope of P1030 was narrowed to focus only on the composition and labelling requirements of electrolyte drinks. Under P1030, FSANZ committed to considering whether to transfer the regulation of electrolyte drinks from Standard 2.6.2 to Standard 2.9.4 as part of P1010 (see section 5 of this consultation paper).

2.2 Australian and New Zealand Food Regulations

2.2.1 Australian and New Zealand Food Laws

The food standards that comprise the Code are enforced by the Australian state and territory and New Zealand Governments through their individual Food Acts. These Food Acts require all food sold in Australia and New Zealand to be *safe* and *suitable*. The Food Acts also require food sold in Australia and New Zealand to comply with any relevant standards in the Code (see section 2.2.5 of this consultation paper). Failure to comply with these requirements is an offence.

2.2.2 Food imported into Australia

The Imported Food Control Act 1992 (IFC Act) requires all food imported into Australia to be safe and to comply with the standards that comprise the Code. Under the IFC Act, importers are legally responsible for ensuring the foods they import comply with the standards that apply to their products and do not pose a risk to human health.

The IFC Act provides for the Imported Food Inspection Scheme (IFIS) which is administered by DAFF. The *Imported Food Control Regulations 2019* sets out how the IFIS operates including the rates that foods are referred for inspection. For the operation of the IFIS, foods are either classified as risk food and are scheduled in the Imported Food Control Order 2019 or are surveillance food.

Orders to classify food are made by the Minister for Agriculture, Fisheries and Forestry based on risk advice from FSANZ. Food may be classified as risk food if FSANZ advises that the food has the potential to pose a medium to high risk to public health.

The IFC and its operation - and that of the IFIS - are outside of FSANZ's remit and out of scope for P1010.

2.2.3 Food imported into New Zealand

Foods imported into New Zealand are subject to requirements of the *Food Act 2014* (the Food Act) and the *Food Regulations 2015* (the Food Regulations), which include complying with the Code. The Food Regulations set out two categories (High Regulatory Interest Food and Increased Regulatory Interest Food) that may require written clearance for entry into New Zealand. Food not in one of these two categories does not require clearance.

The Food Act 2014 and regulations are outside of FSANZ's remit and out of scope for P1010.

2.2.4 Food Standards Australia New Zealand Act 1991

The FSANZ Act sets out the process for developing and amending food standards for Australia and New Zealand.

Section 18 of the FSANZ Act sets out the three primary objectives, in descending order of priority, that FSANZ is required to consider in developing or varying a food standard. These are:

(a) the protection of public health and safety;
(b) the provision of adequate information relating to food to enable consumers to make informed choices; and
(c) the prevention of misleading or deceptive conduct.

Section 18 also provides that, when developing and varying standards, FSANZ must also have regard to:

(a) the need for standards to be based on risk analysis using the best available scientific evidence;
(b) the promotion of consistency between domestic and international food standards;
(c) the desirability of an efficient and internationally competitive food industry;
(d) the promotion of fair trading in food; and
(e) any written policy guidelines formulated by the Australia and New Zealand Food Regulation Ministerial Council[1].

[1] Now known as the Food Ministers' Meeting; previously the Australia and New Zealand Ministerial Forum on Food Regulation.

Section 59 of the FSANZ Act provides that, in assessing a proposal (such as P1010), FSANZ must have regard to the matters:

(a) whether costs that would arise from a food regulatory measure (such as a Standard or variation to the Code) developed as a result of the proposal outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure;
(b) whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the proposal;
(c) any relevant New Zealand standards;
(d) any other relevant matters. The latter include the objectives listed in section 18.

2.2.5 Australia New Zealand Food Standards Code (the Code)

As stated in section 2.2.1 of this consultation paper, foods sold in Australia and New Zealand must comply with relevant Australian state or territory or New Zealand food laws, which, among other things, require compliance with the Code.

The scope of Proposal P1010 is solely on the regulation of sports foods under the Code. Sports foods sold in Australia and New Zealand must meet the composition and labelling requirements of general foods set out in the Code where applicable as well as the specific provisions in Standard 2.9.4 and Schedule 29. The former include the requirements in subsections 1.1.1—10(5) and 1.1.1—10(6) of the Code which require that a food for sale must not consist of, or have as an ingredient or a component, a novel food, a food used as a nutritive substance[2], food produced using gene technology, food additives and processing aids, unless expressly permitted by the Code (this list here is not all of the ingredients listed in the Code, but are the most likely substances relevant to sports foods). Ingredients or components fitting the categories listed in these sections require an application to change the Code.

2.2.5.1 Applications to change the Code: pre-market assessment

Consistent with FSANZ's primary objective as stated in the Act, the purpose of pre-market assessment is to evaluate the potential risks to public health and safety if a new food or substance were to be in the food supply.

All new food, including substances, listed in subsections 1.1.1—10(5) and (6) are subject to a statutory assessment by FSANZ, in accordance with the FSANZ Act, which evaluates the potential impact of permitting the food or substance on, among other things, public health and safety, and in the case of sports foods, assesses alignment with the defined purpose of the product or food set out in Standard 2.9.4[3].

In assessing the public health and safety of new food, including substances, FSANZ considers a variety of toxicological and nutritional aspects together with information about its chemistry and how much of it would typically be consumed. This process ensures the safety of new foods before they can be made available in the Australian and New Zealand food supply.

2.2.6 New Zealand Supplemented Food Standard

New Zealand food law includes the *New Zealand Food (Supplemented Food) Standard 2016* (SFS).

[2] A definition for 'used as a nutritive substance' is given in section 1.1.2—12. Permissions for the use of nutritive substances other than vitamins and minerals in FSSF are listed in section S29—19.
[3] Chapter 3.3 of the FSANZ Application Handbook.

The SFS and Standard 2.9.4 operate alongside each other in New Zealand to regulate sports foods. In New Zealand, sports food manufacturers and distributors have the choice to position their products as FSSF under the Code or as 'supplemented foods' under the SFS. The SFS and its operation is outside of FSANZ's remit and is out of scope for P1010.

The SFS is a New Zealand-only standard made under the New Zealand *Food Act 2014*. The SFS is not part of the Code.

The SFS applies to supplemented food that is manufactured, sold, or prepared for sale in New Zealand or imported into New Zealand for sale. For SFS purposes, a supplemented food is a product that is represented as a food that has a substance or substances added to it, or that has been modified in some way, to perform a physiological role beyond the provision of a simple nutritive requirement. Although not an exhaustive list, the SFS provides the following products are not supplemented foods:

- a dietary supplement (as defined in the New Zealand Dietary Supplements Regulations 1985)
- a medicine (as defined in the New Zealand *Medicines Act 1981*)
- a controlled drug or restricted substance (as defined in the New Zealand *Misuse of Drugs Act 1975*)
- a formulated meal replacement or formulated supplementary food (as defined in section 1.1.2—3 of the Code) and
- a formulated caffeinated beverage (as defined in section 1.1.2—6 of the Code).

The SFS requires supplemented foods to comply with the majority of standards in the Code. These do not include Standard 2.9.4.

The SFS permits a range of substances such as vitamins, minerals, food additives, processing aids other substances (such as caffeine) to be added to supplemented foods at certain levels. These permissions and levels differ to those set by the Code for sports foods. In general, unless it is specifically restricted or prohibited in the SFS itself, any vitamin, mineral, botanical or bioactive substance may be added to a supplemented food provided that it is safe and suitable for the purpose that it is being added. The SFS remains subject to the overarching requirement of the New Zealand Food Act that all additions to supplemented foods must result in food that is safe and suitable.[4]

2.2.7 Trans-Tasman Mutual Recognition Arrangement

The Trans-Tasman Mutual Recognition Arrangement (TTMRA) is a non-treaty arrangement between the Australian (Commonwealth) Government, the state and territory governments of Australia, and the Government of New Zealand. A key principle of the TTMRA is mutual recognition whereby goods that can legally be sold in New Zealand can be imported into and sold in Australia, and vice versa. All laws – including food laws – are subject to the TTMRA unless specifically excluded or exempt. The TTMRA took effect on 1 May 1998 and is implemented in Australia by the *Trans-Tasman Mutual Recognition Act 1997.*

The TTMRA allows supplemented foods that comply with New Zealand food law (including the SFS) in New Zealand to be imported into and sold in Australia.

Foods manufactured and sold in Australia are not subject to the TTMRA and must comply

[4] Supplemented Food Standard User Guide

with Australian food laws including the Code.

The TTMRA and its operation is outside of FSANZ's remit and is out of scope for P1010.

2.2.8 Interaction with Australian Therapeutic Goods Regulations

The regulation of sports foods in Australia can fall within what is known as the 'food-medicine interface' (FMI). The FMI arises out of the definitions in Australian food laws as to what is 'a food' and in the *Therapeutic Goods Act 1989* (TG Act) as to what is a therapeutic good. These generally provide that: anything that is a therapeutic good – as defined and regulated by the TG Act – is not a food; and anything that is traditionally used as a food or for which there is a standard in the Code is not a therapeutic good. This means that, for regulatory purposes, a product must either be a food regulated by food laws or a therapeutic good regulated by the TG Act – it cannot be both.

There can be products – including sports foods – where initially it may not be clear whether they are a therapeutic good or a food, and therefore which set of regulation they are subject to. Often, claims made about a product, or the appearance of the product, may suggest that it is a therapeutic good. However, the fact that certain claims are made about a product does not automatically make it a therapeutic good, nor if the product comes in capsules or powders, or is labelled as a 'supplement'. In such cases, the different regulatory requirements means that regulators, manufacturers, importers and consumers need to know whether the particular product is to be regulated as food or as a medicine (or a therapeutic good).

In light of the above, the TGA has developed, published on its website and administers an interactive Food Medicine Interface Guidance Tool[5] to determine whether a product is a food or therapeutic good.

The FMI and definitions in the TG Act and Food Acts are outside of FSANZ's remit and are out of scope for P1010.

2.2.8.1 Section 7 TGA Declaration

The TGA has declared under section 7 of the TG Act that certain sports supplements are therapeutic goods for the purposes of that Act (and therefore not a 'food'). The declaration came into effect on 30 November 2020[6].

The declaration provides that goods that meet the following criteria are 'therapeutic goods' and subject to regulation under the TG Act:

Goods for oral administration that are represented (expressly or by implication) as being for the improvement or maintenance of physical or mental performance in sport, exercise or recreational activity, and that:

(a) contain, or are represented (expressly or by implication) to contain, one or more of the following substances (however described or named):
  (i) a substance included in a schedule to the current Poisons Standard; or
  (ii) a substance expressly identified on the Prohibited List[7] that is added as an ingredient to the goods; or
  (iii) a relevant substance that is added as an ingredient to the goods; or

[5] Food-Medicine Interface Guidance Tool, Therapeutic Goods Administration
[6] *Therapeutic Goods Act 1989*
[7] Prohibited List means *The World Anti-Doping Code International Standard Prohibited List* (January 2020) published by the World Anti-Doping Agency, as in force or existing at 30 November 2020.

(iv) a substance with equivalent pharmacological action to a substance mentioned in subparagraph (i), (ii) or (iii), including those that may be characterised as an active principle, precursor, derivative, salt, ester, ether or stereoisomer; or

(b) on or after 30 November 2020 are supplied in the dosage form of a tablet, capsule or pill other than those goods containing glucose only when the goods are used, advertised, or presented for supply:

(a) for therapeutic use; or
(b) in a way that is likely to be taken to be for therapeutic use;

including, but not limited to, one or more of the following therapeutic uses:

(c) gaining muscle;
(d) increasing mental focus;
(e) increasing metabolism;
(f) increasing stamina;
(g) increasing testosterone levels, reducing oestrogen levels or otherwise modifying hormone levels;
(h) losing weight or fat;
(i) preparing for workout;
(j) recovering from workout.

The operation of the TG Act and section 7 declarations are matters that fall within the responsibility of the TGA and are outside of FSANZ's remit. As such, they are out of scope for P1010.

2.2.9 Australia New Zealand Food Regulation Ministerial Policy Guideline

FSANZ must have regard to guidelines developed by the Food Ministers' in reviewing, developing and varying standards in the Code. The relevant policy for the purposes of P1010 is the Policy Guideline on intent of Part 2.9 – Special Purpose Foods of the Australia New Zealand Food Standards Code[8].

The Specific Policy Principles of the guidelines are:

Food Standards contained within Part 2.9 of the Code should maintain a clear distinction between special purpose foods and other foods as regulated elsewhere in the Code.

In particular:

- Special purpose foods should be targeted only to those population groups satisfying the definition presented in the Scope/Aim section.
- The composition of special purpose food should be consistent with the intended purpose.
- Adequate information should be provided, including through labelling and advertising of special purpose foods, to:
    - assist consumer understanding of the specific nature of the food, the intended population group and intended special purpose of the food; and
    - provide for safe use by the intended population and to help prevent inappropriate use by those for whom the special purpose food is not intended.

[8] Policy Guideline on the Intent of Part 2.9 - Special Purpose Foods

- Consideration, where appropriate, should be given to application of controls to restrict access to a special purpose food on the basis of risk to public health and safety.

Additional policy guidance provides that where relevant, standards contained in Part 2.9 of the Code should be consistent with internationally recognised codes of practice, such as Codex and World Health Organization (WHO) recommendations/guidelines, relating to the manufacture and/or labelling of special purpose foods.

2.3 International Regulations

Regulations vary internationally and at present, sports foods are rarely regulated as foods that are used exclusively for sports performance. Countries more commonly categorise sports-related products either within their general food regulation provisions or as broadly defined special purpose foods, dietary or nutritional supplements.

2.3.1 Codex

The Codex Alimentarius Commission (Codex) is the international food standards setting body established by the United Nation's Food Agriculture Organization (FAO) and the WHO. There is no specific Codex food standard for sports foods, however several generic Codex standards and guidelines contain provisions for labelling, claims and vitamin and mineral supplements which are relevant.

The Codex Guidelines for Vitamin and Mineral Food Supplements[9] covers supplements in forms such as capsules, tablets, powders, and solutions, the latter two are similar to foods regulated under Standard 2.9.4. Minimum levels of addition for vitamins and minerals are set at 15% of the recommended daily intake and maximum amounts are based on upper safe levels established by scientific risk assessment.

The Guidelines align the labelling requirements for vitamin and mineral food supplements with other Codex labelling requirements. The labelling requirements include naming the product 'food supplement', providing vitamin and mineral information, the recommended quantity and frequency of use, and a statement that the product should be stored out of reach of young children.

The *General Principles for the Addition of Essential Nutrients to Foods*[10] addresses the appropriate nutrient composition of a special purpose food, and adding essential nutrients to foods for restoration, nutritional equivalence and fortification purposes.

2.3.2 European Union

Within the European Union (EU), sports foods are primarily regulated at the national level. In July 2016, the European Commission (EC) declared that sports foods will be considered as 'foods for normal consumption' (as opposed to sports-specific foods)[11] and thus regulated as either a food supplement[12] or fortified food[13].

Sports related foods in the EU must comply with several horizontal food laws (general rules

[9] Codex Guidelines for Vitamin and Mineral Food Supplements
[10] Codex (1991) General principles for the addition of essential nutrients to foods (CAC/GL 1-1987)
[11] Report from the Commission to the European Parliament and the Council on Food Intended for Sportspeople (2016)
[12] Food Supplement Definition (Real Decreto 1487/2009): Food products whose purpose is to complement the normal diet and consisting of concentrated sources of nutrients or other substances having a nutritional or physiological effect, in simple or combined form, marketed in dosage form, i.e. capsules, pills, tablets, pills and other similar forms, powder sachets, liquid ampoules, dropper bottles and other similar shapes of liquids and powders to be taken in small unit quantities.
[13] EC Regulation 1925/2006 on the addition of vitamins and minerals and or certain other substances to foods

addressing common aspects for 'foodstuffs'), nutrition and health claim labelling[14,15,16,17,18] and novel foods[19]. For example, as per EC Regulation 1925/2006 *(fortified food)*, 'when a vitamin or a mineral is added to foods the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold shall not exceed maximum amounts'. However, maximum amounts are yet to be set. Further, the addition of a vitamin or a mineral to a food 'shall result in the presence of that vitamin or mineral in the food in at least a significant amount where this is defined according to the Annex to Directive 90/496/EEC'.

2.3.3 United States

In the United States (US), sports foods are classified as dietary supplements. Some of the sports foods and drinks typical of those on the market in Australia and New Zealand would be regulated as food and others as dietary supplements in the US. Dietary supplements in the US may be found in many forms, such as tablets, capsules, powder, liquids and bars.

The US Food and Drug Administration (FDA) regulates both finished dietary supplement products and dietary ingredients. This regulation is different to those covering general foods and medicines. The US *Federal Food, Drug, and Cosmetic Act* (FD&C Act) was amended in 1994 by the *Dietary Supplement Health and Education Act* (DSHEA), which defined 'dietary supplement' and set out the FDA's authority regarding such products. Under existing law the FDA does not have the authority to approve the safety, effectiveness or labelling of dietary supplements before they are sold to the public.

The FD&C Act requires that manufacturers and distributors who wish to market dietary supplements that contain 'new dietary ingredients' that have not been present in the food supply as an article used for food, or a dietary supplement containing such a new dietary ingredient, must notify the FDA about these ingredients. Generally, the notification must include information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe under conditions of use recommended or suggested in the labelling.

The FDA's role in regulating dietary supplements typically begins after the product enters the marketplace. The FDA periodically inspects manufacturing facilities to ensure they meet applicable manufacturing and labelling requirements; reviews product labels and other labelling information to ensure products are appropriately labelled and do not make claims that render the products as drugs; and monitors adverse event reports and other product complaints for information about the safety of products. If a product is found not to comply, the FDA can work with the company to bring the product into compliance or ask the company to voluntarily recall the product. The FDA also has the authority to take action to remove a dangerous product from the market.

The FDA prohibits a small number of ingredients[20] such as androstenedione, dimethylamylamine (DMAA) and ephedra. The FDA Dietary Supplement Ingredient Advisory List[21] also works to alert the public when the FDA identifies an ingredient of concern in products marketed as dietary supplements but these products can remain on the market.

This way of regulating foods (including sports foods) in the US means there can be significant differences in the composition and labelling of sports foods between the US,

[14] Regulation (EU) 1169/2011 on the provision of food information to consumers
[15] EC Regulation 1924/2006 on nutrition and health claims made on foods
[16] European Commission, Addition of Vitamins and Minerals
[17] EC Regulation 1925/2006 on the addition of vitamins and minerals and or certain other substances to foods
[18] Regulation (EU) 1169/2011
[19] Regulation (EU) 2015/2283 on novel foods

[20] FDA, Dietary Supplement Products & Ingredients (2022)
[21] Dietary Supplement Ingredient Advisory List | FDA

Australia and New Zealand.

2.3.4 Canada

Health Canada classifies sports foods as dietary supplements and regulates them as Natural Health Products (NHP). All NHPs must have a product license before they can be sold in Canada. There are three streams of approval for NHPs, with varying assessment timeframes depending on whether a Canadian monograph exists. An NHP monograph for sports supplements[22] provides a list of what these products can contain. The monograph allows for different requirements regarding composition than those offered in the Code.

2.3.5 Singapore

The *Sale of Food Act: Food Regulations*[23] in Singapore contain general provisions for the addition of nutrient supplements and for claims. Only nutrient supplements (amino acids, minerals or vitamins) listed in a schedule may be added to foods, except for special purpose foods. Claims for the presence of vitamins and minerals, and nutrition claims are regulated. A nutrition claim can be made if it is not false or misleading and the label must not imply consuming the food will achieve health or improve a physical condition. Official guidelines are available for nutrition and health claims.

The Regulations include standards and particular labelling requirements for many standardised foods including special purpose foods and non-alcoholic drinks. The Regulations for special purpose foods include energy food and formulated food and do not appear to include any specific provisions for these foods.

It is likely that some of the sports food products typical of those on the market in Australia and New Zealand could be regulated in Singapore by the general provisions for non-standardised foods and others as special purpose foods.

2.3.6 Malaysia

The Malaysian Food Regulations do not contain specific provisions for sports food products. The regulations permit the addition of 'added nutrients' which includes any vitamin, mineral, amino acid, fatty acid, nucleotide or other food components which, when added singly or in combination to food, improves the nutritional value of the food. The Regulations refer to a schedule listing permitted added nutrients.

2.3.7 Japan

Food is regulated in Japan under the Japanese Agricultural Standards Law, the Food Sanitation Law, and the Health Promotion Law. There are additional regulatory provisions for health foods which might include some of the Australian and New Zealand sports food products. Health foods include dietary supplements, food with nutrient function claims and food for specified health uses which are allowed to indicate claims for specified dietary uses. The nutrition labelling and health claims system sits under the Health Promotion Law and includes food with nutrient function claims and food for specified health uses (FOSHU). Several hundred FOSHU approved- products are currently on the market in Japan. Foods for special dietary uses (FOSDU) are another category of foods in Japan.

[22] Ingredient Search (hc-sc.gc.ca)
[23] Singapore Sale of Food Act: Food Regulations

3 Relevant Considerations

3.1 Market Overview

The sports food industry is complex and has grown rapidly over the last decade. Globally, the range has expanded from conventional rehydration drinks to an array of bars, powders and supplements that suggest they can boost energy, aid recovery, build muscle and burn fat. Advances in research and technology have led to innovation in products and the use of non-traditional ingredients.

Much of the available market data is out-dated and FSANZ understands there may have been significant shifts since then. FSANZ is seeking new data to inform its understanding of the current market.

3.2 Global Market

The global market for sports foods increased from US $27.8 billion in 2007 to an estimated $31.2 billion in 2008. At the time, sports food represented the second-largest market segment, generating an estimated $1.5 billion in 2008[24].

At the time, growth in this market was thought to be primarily driven by an increased consumer focus on health and wellness, improving income levels, consumer demand and product innovation. Population growth and improving economies in emerging markets such as China, south-east Asia and Latin America was also expected to increase the demand for nutritional products, and in particular, sports food products.

From 2004 to 2018, the global sports food market grew 190% at a compound annual growth rate (CAGR) of 7.9%[25], an unprecedented growth rate to sustain for this type of consumer good. The Asia-Pacific region was expected to see the fastest growth rate overall between 2018 and 2023, with a CAGR of 9.1% predicted. At the time of the report, the global 'sports nutrition' market size was expected to reach ~AU $64 billion (US $44 billion) by 2021.

It is however difficult to obtain accurate information on the sports food product market as goods may be categorised as food, beverages, supplements or therapeutics. Sports food products are widely available across the world and can be purchased from supermarkets, service stations and convenience stores, gyms, health food stores, specialist supplement stores, and sporting venues. While data are available for products purchased in supermarkets, other retail outlet sales and online sales are harder to track.

3.2.1 Australian market

In late 2010, FSANZ surveyed a small number of Australian sports food manufacturers and importers to gain an overview of the sports food industry in Australia. Further information on the value of sports food products purchased from supermarkets was also obtained from the *Retail World Annual Report 2010*.

While industry data were available for products purchased from supermarkets, there were limited data on products purchased from other retail outlets. At the time of the survey, industry stakeholders estimated the total value of the market to be from $110 million to as high as $600 million[26].

According to industry sources, approximately 40% of sports foods were purchased through specialist shops, health food stores or pharmacies. These products were predominantly

[24] Sports Nutrition and High Energy Supplements: The Global Market Report Code: FOD043A, Published: September 2008.
[25] Sports nutrition is expanding across consumers, categories, and positioning | Nutritional Outlook Accessed 28112022
[26] Industry respondents to a FSANZ survey of the Australian sports food market conducted in late 2010.

powders and supplements. Approximately 25% of products were purchased through supermarkets. Service stations accounted for around 25% of retail sales, which were mainly sports drinks. The remaining 5% of sales occurred through gyms, clubs, or personal trainers. Products purchased 'online' or imported for personal use were considered outside the scope of the survey, but were reported to be increasing.

The *2010 Retail World Annual Report* indicated that the total value of sports foods purchased from supermarkets was approximately $158 million. Sports foods[27] (not drinks) were valued at $37.8 million, an increase of approximately 14% from the previous year.

A 2020 report by Complementary Medicines Australia[28] stated that 'sports nutrition' contributed approximately AU $1.31 billion out of AU $5.6 billion revenue for complementary medicines in Australia per year (note another AU $3.1 billion was attributed to vitamin and dietary supplements). This figure could include sports drinks and some therapeutics (listed medicines).

3.2.1.1 Local and imported products

Industry respondents to the FSANZ 2010 industry survey mentioned above advised that approximately 70% of sports products were manufactured locally while the remaining 30% were imported. However, this varied depending on the product category. For example, some industry sources advised that up to 70% of products specifically targeting the body building industry were imported, predominantly from the US. Possible reasons suggested for this included strengthening of the Australian dollar at the time and availability of a wider range of products to meet consumers' needs. Some survey respondents noted that products manufactured in, or imported into New Zealand under the *Dietary Supplement Regulations* (1985) or the NZ *Food (Supplemented Food) Standard (2010)* were being exported to Australia via the TTMRA. However, it was reported that many of these products contained substances not currently permitted or at higher levels than the current permissions in Standard 2.9.4. These products competed directly with Australian manufactured or other imported products which needed to comply with the Code.

3.2.1.2 Export products

A small number of Australian manufacturers advised that they exported a range of products to New Zealand, mainly protein powders, amino acid blends, bars and sports drinks. One manufacturer advised that the value of this segment of the market was approximately AU $9 million.

3.2.2 New Zealand Market

In March 2010, FSANZ also engaged a consultant to undertake a survey of New Zealand sports food manufacturers and importers to gain an overview of the sports food industry in New Zealand. The consultant's report forms the basis of the information below on the New Zealand sports food market.

More recent data from a 2014 report by Statista estimated the total market size of sports nutrition products amounted to NZ $47 million per year. This included protein powders, ready-to-drink (RTD) protein drinks, non-protein based drinks, protein bars and other protein-rich foods.

[27] Included bars, protein or protein/energy powders and drinks (other than electrolyte drinks) and sport-related nutritional capsules or tablets.
[28] CMA Industry Snapshot 2020

3.2.2.1 Value

The 2010 survey found there was rapid growth in the market for sports food products in New Zealand over the decade prior. The total value of sports drinks, sports bars and nutritional sports supplements was conservatively estimated to be NZ $71 million[29]. Industry sources estimated that supermarket sales made up approximately 52% of the total sports food market in New Zealand. The remaining 48% represented products purchased from service stations, convenience stores, gyms, pharmacies, fitness centres, stores servicing the body-building sector, and health food stores. These figures excluded internet sales.

Sports bars and supplements were valued at NZ $46.3 million, which is approximately 65% of the retail market for sports food products in New Zealand. NZ $28 million (39%) was the value of products purchased in convenience, sports or health food stores while NZ $18.3 million (26%) was spent in supermarkets.

Products included protein powders, protein bars and specialty supplements.

3.2.2.2 Local and imported products

Based on the product survey, approximately 40% of products were manufactured locally. Of the 60% imported brands, the majority were manufactured in the United States and Canada, while the remaining brands came from Australia, Germany, South Africa and Switzerland. However, the percentage of imported products varied with the product category. Some respondents noted that a large majority of ready-to-drink beverages was manufactured in New Zealand. Others informed FSANZ that dietary supplements were mainly imported while about half the protein powder products were imported and half were manufactured locally.

3.2.3 Questions

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 sports food market in Australia, New Zealand or globally?

4 Regulatory Considerations

FSANZ's highest priority is to protect the health and safety of consumers though the assessment of risk to target and non-target groups. The development of effective regulatory measures that are easy to understand and enforceable aims to provide clarity for industry, consumers and enforcement agencies.

4.1 The purpose of Standard 2.9.4

4.1.1 Special purpose vs general purpose foods

The high-level purpose of foods is one of the fundamental concepts underpinning the Code and is of particular importance to the regulation of sports foods. Historically, only two broad categories of purpose were tacitly recognised in food regulation – special purpose foods (Part 2.9 of the Code) and general purpose foods (Chapter 2 except Part 2.9 of the Code).

4.1.1.1 General purpose foods

The Code does not contain a definition of what is a general purpose food. Its approach is to

[29] Based on retail data supplied by an industry stakeholder.

impose requirements that apply to any food for sale, consistent with the Food Acts, and then to set particular composition and labelling requirements for those foods for sale that fall within certain definitions or categories (i.e., special purpose foods, novel foods, prohibited or restricted plant etc).

4.1.1.2 Special purpose foods

The policy guideline on intent of Part 2.9 – Special Purpose Foods of the Australia New Zealand Food Standards Code (the Policy Guideline) distinguishes between special purpose foods covered by Part 2.9 of the Code and other food regulated elsewhere in the Code.

The Policy Guideline specifies the target population for special purpose foods as 'physiologically vulnerable individuals and population sub-groups' in situations where there is risk of dietary inadequacy to support:

- physical and physiological need arising from specific life stages (e.g. infancy), physical disease, disorder and disability; or
- physical and physiological conditions that require altered energy intake;

that occasion the use of special purpose food'.

The Policy Guideline also states that requirements within Part 2.9 of the Code are prescribed relative to the particular intended dietary use of the food.

4.2 Definitions

In the Code, an FSSF is a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals. As 'special purpose' foods, FSSF may contain specified ingredients which are either not permitted to be added to 'general purpose' foods and drinks or are permitted to be added at a different level. FSSF are intended as supplementary to a diet rather than for use as the sole or principal source of nutrition.

The sports foods definition in the Code determines what the compositional and labelling requirements apply to. While the definition of ***formulated supplementary sports food*** (section 1.1.2—3 and noted in section 2.9.4—2) and ***one-day quantity*** (section 1.1.2—2 and noted in section 2.9.4—2) are the only two definitions under review for P1010, the contents of Standard 2.9.4 is shaped by several other overarching definitions (see Table 1). Any changes to the in scope definitions will need to be made with consideration to other related definitions used throughout the Code. Note that Standard 2.9.4 also includes several definitions in Division 3 regarding labelling and composition that are not included here but discussed in section 6.1.6 of this consultation paper.

Table 1: Current definitions relevant to Standard 2.9.4

Document	Definitions related to formulated supplementary sports foods
Section 1.1.2— 3 Definition used throughout the Code and noted in section 2.9.4—2	***formulated supplementary sports food*** means a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals.
Section 1.1.2— 2 Definition used throughout the Code	***Average energy content*** means the average energy content calculated in accordance with section S11—2.
Section 1.1.2—2 Definition used throughout the Code and	***one-day quantity*** in relation to a formulated supplementary sports food, means the amount of that food which is to be consumed in one day in accordance with directions specified

noted in section 2.9.4—2	in the label.
Section 1.1.2—12 Definition used throughout the Code	Definition of ***used as a nutritive substance*** (1) In this Code, a substance is used as a nutritive substance in relation to a food if it is added to the food: (a) to achieve a nutritional purpose; and (b) it is a substance identified in subsection (2). (2) For subsection (1), the substances are: (a) any substance that is identified in this Code as one that may be *used as a nutritive substance; and (b) a vitamin or a mineral and (c) any substance (other than an inulin-type fructan, a galacto-oligosaccharide or a substance normally consumed as a food) that has been concentrated, refined or synthesised, to achieve a nutritional purpose when added to a food. Note: Provisions that control use of substances as nutritive substance are in Standard 1.1.1, Standard 1.3.2 (Vitamins and minerals), Standard 2.9.1 (Infant formula products), Standard 2.9.2 (Food for infants), Standard 2.9.3 (Formulated meal replacements), Standard 2.9.4 (Formulated supplementary sports foods) and Standard 2.9.5 (Food for special medical purposes). Substances referred to in paragraph (2)(a) include, for example, those that are identified in the tables to sections S17—2 and S17—3 (vitamins and minerals) and the tables to sections S28—2, S29—18 and S29—19 (other substances).

4.2.1 Defined population and purpose

As mentioned above, a special purpose food typically has a defined population. The definition of an FSSF currently within section 1.1.2—3 was developed in the 1990s and the industry and consumer base has evolved significantly over the past 20-30 years (see section 2 of this consultation paper). In its current wording, this definition explains that FSSF is food *specially formulated to assist sports people in achieving specific nutritional or performance goals*. If a food meets the definition of FSSF, it must comply with the compositional and labelling requirements that apply to FSSF.

Based on the above, sports foods, if regulated as FSSF, are thus presently intended to be:

- specially formulated
- designed to meet the health needs of a particular sub-group, noting there is no explicit definition of *sports person* in the Code and thus, the ordinary meaning of that term applies i.e. a person who takes part in sport
- consumed for the delivery of nutrients at higher levels than current permissions and other substances not currently permitted.

In reviewing the wording of the definition of sports foods in Standard 2.9.4, there are several considerations. The definition must be framed in a way that recognises and is consistent with the legislative distinction between what constitutes a food and what constitutes a therapeutic good (see section 2.2.8 in this consultation paper).

Second, the definition provides guidance on the nature of assessment undertaken by FSANZ when considering the safety and suitability of new substances (via applications). For example, in the case of new nutritive substances, section 3.3.3 of the Application Handbook

requires evidence of a nutritional purpose[30] i.e. to demonstrate purpose relative to that which is outlined in the definition of a "substance used as a nutritive substance" in section 1.1.2—12 of the Code. At present, the definition of an FSSF, as mentioned above, is specific to a person *achieving nutritional or performance goals*.

Finally, FSANZ notes that it is arguable that consumers who are not elite or professional 'sports people' could viably be a part of this population group if they are exercising regularly (i.e. to the extent that the latter results in physical and physiological conditions that require altered energy and nutritional intake). In this context, the term 'sports people' may no longer be appropriate.

4.2.2 Regarding the definition of a 'one-day quantity'

The current definition in the Code of a 'one-day quantity' refers to *the amount of that food which is to be consumed in one day in accordance with directions specified on the label.* The definition relates specifically to FSSF and the amount of FSSF consumed in one day. It does not relate to the daily amount consumed by a person from all food in one day. There are two issues that FSANZ is aware of with this definition in the context of the current sports foods market.

A social science literature review conducted in 2013 by FSANZ suggested that a subset of consumers are frequently taking more than one sports food product at the same time. An example of how this may be happening is via the emerging practice of 'stacking'. Stacking is when consumers are encouraged to use multiple products before, during and after a workout and sometimes several times a day (i.e. during the workout and/or then between meals for the rest of the day). This often includes three to four products including a fat burner or stimulant, a protein powder, a creatine or carnitine powder and/or a branched-chain amino acid (BCAA) blend. 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. Some products are promoted such that when taken individually, are compliant with the Code, but when taken as part of a 'stack' may contribute to exceeding the maximum one-day quantity and sometimes the Upper Level of Intake (UL).

For example:

Product One (Protein Powder): Includes multiple forms of carnitine in a 'proprietary blend' in unknown quantities and listed on the NIP as a proprietary blend.

Product Two (Fat Burner): comprised L-carnitine sold on its own which was compliant for one serve (1 g allowable in the Code) but to the side of the NIP recommends taking 1-3 serves per day. Over one serve per day is non-compliant with the Code and alongside the protein powder, which includes a proprietary blend of three different forms of L-carnitine of unknown quantities, far exceeds the maximum permitted amount.

Product Three (Amino acids): Compliant with the Code and does not exceed any maximum permitted one-day quantity when assessed against all other products in the stack.

Product Four (L-glutamine): comprises L-glutamine sold on its own with one serve being compliant at 3 g.

[30] Section 3.3.3 A (A1) of the FSANZ Application Handbook

4.2.3 Questions

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?

Q3. For industry and regulators, how should proprietary blends or stacks best be regulated and why?

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

4.3 Current compositional permissions

In order to gather broad views on the standard, this paper has asked questions so far on the sports food market (section 3 of this consultation paper), definitions and the overarching definition within the standard (section 4.2 of this consultation paper). Together, this will provide direction regarding the type and nature of foods that may eventually be permitted in a revised version of Standard 2.9.4.

As outlined above, Standard 2.9.4 permits the addition of vitamins, minerals and electrolytes such as sodium and potassium, amino acids and a small range of other nutritive substances to sports foods. The levels of vitamins and minerals are controlled based on relative risk either indirectly by permitting a maximum claim, or directly by permitting a maximum amount.

Review of the standard will include a review of all substances already permitted under Standard 2.9.4 as well as a risk assessment of any other substances that FSANZ is considering for inclusions in sports foods.

In recognition of the growth in product availability, in 2021 FSANZ conducted a Call for Data seeking technical and safety information on new or existing substances to be considered for addition to Standard 2.9.4. The data provided is under review and will assist FSANZ in considering the compositional requirements of sports foods, ensuring that any changes in permissions are underpinned by evidence-based scientific assessment, in accordance with the FSANZ Act. Much of this work on individual substances will be incorporated in the 1st and 2nd Call for Submissions.

This consultation paper is not requesting further technical and safety information, rather FSANZ is seeking input on the regulatory framework used in Standard 2.9.4 relating to compositional permissions.

4.3.1 Permitted forms

Permitted forms of substances added to sports foods in the Code are set out in section 2.9.4–3 – Composition of formulated supplementary sports foods. Permitted forms of vitamins and minerals are also detailed in the table to sections S17–2 or S17–3, S29–17 and the amount of the vitamin or mineral in the food is no more than the amount specified in Column 2 of the table in section S29–16. Permitted amino acids used as nutritive substances are listed in the table to section S29–18 and corresponding maximum amounts specified in Column 2 of the table. Other permitted nutritive substances are set out in the table to section S29–19 and their corresponding maximum amounts specified in Column 2 of the table. In addition, section 2.9.4—3(2) sets limits on sodium and potassium.

There are currently no permissions for analogues or derivatives or other forms of vitamins or minerals other than those listed in the Code e.g. the Code currently permits L–alanine at a maximum amount that may be added to a one-day quantity at 1200 mg but does not permit β-alanine in any quantity. Express permission via an application to amend the Code is

required to permit any analogues or derivatives of substances that are listed in the Code (see section 2.2.5.1 of this consultation paper).

4.3.2 Access and availability

There are no specific constraints set out in Standard 2.9.4 for the purchase of sports foods. The increasingly easy access to and consumption of sports foods by the general population (section 3.2.1 of this consultation paper) means that non-target consumers and vulnerable sub-populations such as children and pregnant women may be accessing and consuming sports foods that are not intended for them. FSANZ has been unable to gather data on the extent of this issue to date.

As outlined in the market overview (section 3 of this consultation paper), innovation and growth are happening quickly. The list of possible novel foods and nutritive substances globally is unknown but likely to be extensive, making prohibitions of high-risk substances beyond those regulated by the TGA difficult. Similarly, emerging scientific evidence may not be appropriate or adequate for determining safety and/or efficacy in the early stages.

As noted above (section 2.3 of this consultation paper), this is addressed in some international regulations by separating 'sports related' foods into either 'foods for general consumption' or a broader category of 'supplemented foods', as opposed to regulating foods specifically for their benefit to sporting performance.

4.3.3 Questions

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)?

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.

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.

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?

Q9. To what extent are vulnerable consumers regularly consuming sports foods? Please provide evidence.

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.

5 Electrolyte drinks

5.1 Regulation of electrolyte drinks

In the Code, ***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'.

Standard 2.6.2 – Non-alcoholic beverages and brewed soft drinks specifies the composition and certain labelling provisions of these general purpose beverages, including electrolyte drinks.

Although considered a sports food by many and implied in the definition, electrolyte drinks are not currently regulated under Standard 2.9.4. The regulation of electrolyte drinks was recently reviewed through Proposal P1030, and at that time the regulation was retained under Standard 2.6.2.

Under Proposal P1030, the original draft variation to the Code prepared in 2014 proposed transferring the regulation of electrolyte drinks from Standard 2.6.2, a general commodity standard, to Standard 2.9.4, a special purpose food standard. This was based on FSANZ's assessment at the time that such a transfer recognised and emphasised the products' special purpose in accordance with the regulatory definition, while noting it was a preliminary step prior to the wider review of Standard 2.9.4.

5.2 Consideration of move from Standard 2.6.2 to 2.9.4

FSANZ received mixed responses to this proposed variation from submitters in 2014. Some submitters regarded electrolyte drinks as special purpose foods whose requirements align more closely with the existing provisions contained within Standard 2.9.4. Whereas some submitters noted that, if a special purpose food, electrolyte drinks would be excluded from the Health Star Rating system and be inconsistent with current marketing and promotion approaches. Some questioned the need for transfer pending the comprehensive review of Standard 2.9.4 while one submitter noted that transfer to Standard 2.9.4 would not reflect the actual range of population usage. Submitters stressed the need for any regulatory change to be underpinned by a robust scientific evidence base.

A 2021 P1030 Consultation Paper proposed amending the 2014 draft variation to retain the regulation of electrolyte drinks in Standard 2.6.2. It was noted that transfer of these provisions to Standard 2.9.4 and the reclassification of electrolyte drinks as special purpose foods, if required, could be further considered as part of the review of sports foods (Proposal P1010).

In responding to the 2021 Consultation Paper for P1030, the industry sector, with the exception of one submitter, supported the retention of electrolyte drinks within Standard 2.6.2. Submitters representing the public health sector also supported the continuation of the regulation of electrolyte drinks under Standard 2.6.2, while acknowledging a move to Standard 2.9.4 could be further considered under Proposal P1010. In contrast, comments received from government submitters were not supportive of the proposed approach, and requested electrolyte drink provisions be aligned with Standard 2.9.4.

After consideration of submissions, FSANZ's position remained that Standard 2.6.2 was the appropriate location in the Code for electrolyte drink permissions at that time. As noted above, transfer to Standard 2.9.4 and reclassification of electrolyte drinks as special purpose foods as part of Proposal P1010 remains an option.

5.3 Questions

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?

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?

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.

6 Labelling

6.1 Current regulations

Food labelling can be used to manage potential risks to public health and safety. It also provides information to enable consumers to make informed choices. Similar to most other foods, sports foods are subject to generic labelling requirements in the Code, unless exempt or where specific requirements apply. Under P1010, FSANZ will consider the application of the generic labelling requirements in the Code to sports foods. Specific labelling issues for the protection of public health and safety and informed choice of relevance to sports foods are outlined below.

6.1.1 Prescribed name

In accordance with subsections 1.2.2—2(1) and 2.9.4—4(2), sports foods are required to be labelled with the prescribed name 'formulated supplementary sports food'.

6.1.2 Directions for use

Information requirements for directions of use, storage and frequency of intake of sports foods are regulated by Standard 1.2.6 and Standard 2.9.4 of the Code, respectively.

Section 1.2.6—2 sets outs the information requirements for directions for use and storage conditions of food for sale. This includes the requirement to provide details of the storage conditions, if these conditions are necessary to ensure the food will keep until the use by or best before date; or if the food must be used or stored in accordance with certain directions for health or safety reasons.

In accordance with Section 2.9.4—4, the label of a sports food must also include *directions stating the recommended amount and frequency of intake of the food* and *a statement of the recommended consumption in one day*.

6.1.3 Warning and advisory statements

Standard 1.2.3 and Schedule 9 include labelling requirements for warning and advisory statements. These statements are required if relevant to the product e.g., a product that contains bee pollen must include an advisory statement that 'the product contains bee pollen which can cause severe allergic reactions'.

Section 2.9.4—4 requires the label of a sports food to include the following required statements:

- 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
- a statement to the effect that the food should be used in conjunction with an appropriate physical training or exercise program; and
- the *warning statement 'Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision'; and
- if the food contains added phenylalanine—the warning statement 'Phenylketonurics: Contains phenylalanine'

Division 3 of Standard 2.9.4 requires products that meet one of three types of compositional specifications (high carbohydrate supplement, protein energy supplement, or energy supplement) to include statements regarding their consumption e.g., for an energy supplement - that the food be consumed with adequate fluid intake (see Table 2 below).

Standard 1.2.1 of the Code includes the labelling requirements for foods required to bear a label or otherwise provide information for foods for retail sale, sold to a caterer and other sales. For sports foods for retail sale that are exempt from the requirement to bear a label, there is currently no requirement in the Code (under Standard 1.2.1 or elsewhere) for the required statements in section 2.9.4—4 to be declared by any other means e.g., displayed in connection with the food or provided to the purchaser on request. This is not consistent with the current approach for the provision of advisory and warning statements in Standard 1.2.1. An example of a situation where a sports food would not be required to bear a label is a drink served in a cup at an event, in the presence of the purchaser.

6.1.4 Nutrition information requirements

Section 1.2.8—5 requires packaged food (unless exempted) to include a nutrition information panel (NIP). Standard 1.2.8 contains other requirements relating to NIPs e.g., what information must be included and how to express that information in a NIP (see sections 1.2.8—6 and 1.2.8—7). This includes the declaration of the average quantity of energy content, protein, fat, saturated fat, carbohydrate, sugars and sodium.

If a claim requiring nutrition information[31] is made about certain nutrients or biologically active substances (on the label or in advertising), the NIP must include the name and the average quantity (expressed in grams, milligrams, micrograms or other units as appropriate) of each nutrient or biologically active substance in respect of which the claim was made (see paragraph 1.2.8—6(1)(d)(iv)). Details of additional substances in the NIP can be voluntarily declared. In most cases, unless the Code otherwise provides, information provided voluntarily in a NIP constitutes a nutrition content claim (subsection 1.2.7—2(3)). Sports foods making a nutrition content claim would need to meet the relevant conditions in Standard 1.2.7 and Standard 2.9.4 of the Code.

6.1.5 Nutrition content and health claims

Nutrition content and health claims about sports foods are regulated by Standard 1.2.7 and Standard 2.9.4.

Standard 1.2.7 and Schedule 4 of the Code set out the conditions under which nutrition content, heath claims and other related claims can be made on food labels and in advertising. 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[32] in nature are not permitted (section 1.2.7—8).

The conditions for making health claims are outlined in section 1.2.7—18. This includes the requirement for the food to which a health claim relates to, to meet the nutrient profiling scoring criterion (NPSC). In accordance with subsection 1.2.7—18(4), special purpose foods standardised under Part 2.9 (including FSSF) do not need to meet the NPSC to make a health claim. More information about claims in relation to FSSF is provided in the sections below.

[31] *claim requiring nutrition information*: (a) means: (i) a nutrition content claim; or (ii) a health claim; and (b) does not include: (i) a declaration that is required by an application Act; or (ii) an endorsement; or (iii) a *prescribed beverage gluten free claim
[32] A claim that refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition

6.1.5.1 Nutritive substance claims

Section 2.9.4—5 requires that if the sports food package includes a statement referring to the presence of a nutritive substance that is not a vitamin or mineral; and the statement is not required by another provision of the Code, the label must either state the amount of the nutritive substance by weight;[33] or list the substance and average quantity by weight of the nutritive substance in the NIP.

As outlined in Section 6.1.4 above, declaration of certain nutrients or biologically active substance in the NIP for a claim requiring nutrition information is a requirement under subparagraph 1.2.8—6(d)(iv) of the Code.

6.1.5.2 Vitamin and mineral claims

The Code does not currently permit sports foods to use any other descriptors (e.g. good source), other than to claim its presence in relation to a nutrition content claim about a vitamin or mineral[34]. In accordance with section 2.9.4—6, FSSF may claim the presence of vitamin and minerals in the sports food only if:

- a serving of the food, or, for a food that requires dilution or reconstitution according to directions, the amount of the food that produces a normal serving, contains at least 10% *RDI or *ESADDI for that vitamin or mineral specified in Column 3 of the tables to sections S1—2 or S1—3, as appropriate; and
- the amount claimed is no more than the amount specified in Column 3 of the table to section S29—16 for that vitamin or mineral.

6.1.5.3 Prohibited representations

Under Standard 1.2.7, foods are permitted to carry health claims, including claims about physical performance, providing certain claim conditions are met. However, section 2.9.4—7 prohibits representations in relation to enhanced athletic performance and beneficial physiological effects to be made on the label on a package of FSSF, as follows:

> *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 to any property or proposed use of the food to enhanced athletic performance or beneficial physiological effects.*

6.1.6 Labelling statements for particular FSSF

If a sports food is a high carbohydrate, protein energy or energy supplement (as defined in Division 3 of Standard 2.9.4), there are requirements for label statements that must or may be provided about their appropriate use and purpose.

A summary of the statements in Division 3, and associated compositional criteria is provided in the table below.

Table 2: Labelling statements for particular formulated supplementary sports foods (Standard 2.9.4, Division 3)

Formulated supplementary sports food	Composition requirements	Required statements	Optional statements (to the effect of)

[33] This amount must be stated either immediately after the statement referring to the presence of the substance; or immediately following the name of the substance in the statement of ingredients (paragraph 2.9.4—5(2)(a)).
[34] The entry in S4—3 for nutrition content claims about vitamin or minerals (not including potassium or sodium) includes a general claim condition that the food is not a formulated supplementary sports food.

category			
High carbohydrate supplement	(a) not less than 90% of the *average energy content of the product is derived from carbohydrate; and (b) more than 15% of the product by weight is *carbohydrate when prepared as directed.	(a) a statement to the effect that, if used during exercise, the food should be consumed in accordance with directions, to avoid the possibility of gastro-intestinal upset; and (b) a statement to the effect that the food must be consumed with an appropriate fluid intake.	(a) the food is useful before, during, or after sustained strenuous exercise; and (b) appropriate usage may assist in the provision of energy in the form of carbohydrates.
Protein energy supplement	(a) not more than 30% and not less than 15% of the *average energy content of the product is derived from protein; and (b) not more than 25% of the average energy content of the product is derived from fat; and (c) not more than 70% of the average energy content of the product is derived from carbohydrate.	a statement to the effect that the food must be consumed with an appropriate fluid intake.	(a) the product may assist in providing a low-bulk diet as may be required during training; and (b) the product may assist in supplementing the diet with a high energy source as may be required during training; and (c) usage as directed may assist in the development of muscle bulk; and (d) the product is useful before, during, or after sustained strenuous exercise.
Energy supplement	not more than 20% of the *average energy content of the food is derived from protein.	(a) a statement to the effect that, if used during exercise, the food should be consumed in accordance with directions, to avoid the possibility of gastro-intestinal upset; and (b) a statement to the effect that the food must be consumed with an appropriate fluid intake; and (c) if more than 30% of the *average energy content of the food is derived from fat—a statement to the effect that the product is a high fat	(a) the product may assist in supplementing the diet with an energy source as may be required during training; and (b) the product is useful before, during or after sustained strenuous exercise.

		food and should be used for special fat loading strategies rather than everyday use.	

6.1.7 Discussion

As outlined above, sports foods are subject to labelling requirements in the Code that address potential risks to public health and safety and enable consumers to make informed choices.

Under P1010, FSANZ will consider the interactions between Standard 2.9.4 and other standards in the Code to determine the generic and specific labelling requirements that should apply to sports foods. This will include consideration of how the requirements of Standard 1.2.7 – Nutrition, health and related claims could apply to sports foods. FSANZ has previously considered claims for sports foods under the 2014 Proposal P1030, which was initially prepared to deliver an interim approach for sports foods and electrolyte drinks pending the future review of Standard 2.9.4. More detail of the revised scope of P1030 is provided in section 5 of this consultation paper.

A more detailed discussion on nutrition and health claims relating to sports foods will occur in a second consultation paper expected in 2023 and will inform the direction of the 1st Call for Submissions. Consideration of required labelling statements (e.g., advisory and warning statements) for sports foods will be undertaken once the formal risk assessment has been completed, and the composition requirements of sports foods have been determined. To help inform our assessment, FSANZ is seeking stakeholder comments on the following questions.

6.1.8 Questions

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.

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.

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.

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.

Q18. Have you identified issues on any other labelling aspects specific to sports foods? Please provide detail.

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?

7 Questions summary

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?

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?

Q3. For industry and regulators, how should proprietary blends or stacks best be regulated and why?

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

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)?

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.

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.

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?

Q9. To what extent are vulnerable consumers regularly consuming sports foods? Please provide evidence.

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.

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?

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?

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.

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.

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.

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.

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.

Q18. Have you identified issues on any other labelling aspects specific to sports foods? Please provide detail.

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?