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P1010 – Review of Formulated Supplementary Sports Foods

Consultation Paper Two - Nutrition and Health Claims

Executive summary

Food Standards Australia New Zealand (FSANZ) is reviewing regulatory requirements for formulated supplementary sports foods under Proposal P1010. Formulated supplementary sports foods (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 apply relating to definitions, calculations, labelling and nutrition and health claims. In the Code, formulated supplementary sports food *means a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals.*

Like most other foods, sports foods are subject to generic labelling requirements in the Code, unless exempt or where specific requirements apply. Standard 1.2.7 – Nutrition, health and related claims was developed under Proposal P293, and was gazetted in 2013. It sets the requirements for making nutrition content and health claims about food. Standard 1.2.7 applies to most foods, and permits foods generally to carry health claims, including about physical performance, providing certain criteria are met. However Standard 2.9.4 has specific requirements for sports foods including a prohibition on representations related to enhanced athletic performance and beneficial physiological effects, and permissions for making certain nutrition claims and statements.

P1010 is reviewing all aspects of Standard 2.9.4. FSANZ released a first consultation paper in January 2023 seeking stakeholder input on the regulatory framework for the standard. The focus of this second consultation paper is the regulation of nutrition content and health claims for sports foods. The paper includes a number of questions to support stakeholders in developing their submissions (see Section 5 for a list of all questions). All submissions to consultation papers released as part of this Proposal will inform FSANZ’s formal assessment and any proposed amendments to the Code.

FSANZ is seeking stakeholder comment on the issues outlined in this consultation paper. Questions for stakeholders have been included in each section, and a summary list in Section 5 of the paper.

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1 Introduction

Formulated supplementary sports foods are specifically regulated within the Australia New Zealand Food Standards Code (the Code) through

- Standard 2.9.4 – Formulated supplementary sports foods
- Schedule 29 – Special purpose foods

Part 2.9 of the Code is intended to contain food standards which prescribe specific requirements for foods for use by physiologically vulnerable individuals and population sub-groups, relative to the particular intended dietary use of the food. A formulated supplementary sports food, as defined in Standard 1.1.2, is *a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals*. In this report, formulated supplementary sports foods are referred to as 'sports foods'.

Proposal P1010 – Review of Formulated supplementary sports foods, aims to ensure that:

- sports foods are safe and suitable for consumers;
- adequate information is available for consumers to make informed choices and not be misled;
- a competitive market for manufacturers is maintained (including domestic and international trade considerations);
- standards are clear to support compliance by manufacturers and enforcement by jurisdictions.

In developing or varying a food standard, FSANZ is required by its legislation to meet its three primary objectives which are set out in section 18 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act). FSANZ's primary objectives, in descending order of priority are: the protection of public health and safety; the provision of adequate information relating to food to enable consumers to make informed choices; and the prevention of misleading or deceptive conduct. FSANZ must also have regard to: the need for standards to be based on risk analysis that used the best available evidence; the promotion of consistency between domestic and international food standards; the desirability of an efficient and competitive food industry; the promotion of fair trading in food; and any applicable Ministerial Policy Guidelines.

P1010 was prepared under subsection 113(6) of the FSANZ Act and is being assessed under the Major Procedure provided by that Act, meaning there will be two legislated public calls for submissions. These have yet to occur. This paper is a non-statutory, additional consultation.

1.1 Reasons for preparing Proposal P1010

Formerly, sports foods were regulated under Standard R10 – Formulated supplementary sports foods of the Australian Food Standards Code. It was gazetted in 1998 and adopted into the joint Australia New Zealand Food Standards Code as Standard 2.9.4 with only minor presentational amendments. Standard 2.9.4 was gazetted in 2000 and was the only standard that was not reviewed when the joint Code came into effect.

Standard 2.9.4 regulates the composition and labelling for both sports foods generally and particular types of sports foods (high carbohydrate supplement, protein energy supplement, energy supplement), provided they conform to specific compositional criteria.

P1010 was formally prepared in 2019 following a request from the Food Ministers' Meeting (then the Australia New Zealand Ministerial Forum on Food Regulation) 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). A full review was requested as a matter of priority to modernise Standard 2.9.4 and to capture the expanding sports supplement market.¹

1.2 P1010 to date

In 2019, FSANZ undertook a scoping study analysing the sports food environment in Australia and New Zealand. The study identified issues relating to regulatory requirements, public health and safety, consumer demand, product composition and industry innovation. This work also identified a need to undertake preliminary non-statutory consultation on substances currently in use in sports foods, the regulatory framework, and nutrition and health claims.

To inform the assessment for the proposal, FSANZ called for data in 2021. We asked interested stakeholders to provide technical, toxicological and nutritional information relating to substances which they consider should be added to or present in contemporary sports foods.² This facilitated early engagement with key industry stakeholders and professional associations, with FSANZ receiving 11 detailed contributions of technical, toxicological and nutritional data.

In January 2023, FSANZ released the first of two non-statutory consultation papers seeking stakeholder views prior to the 1st statutory Call for Submissions (CFS). In the P1010 Consultation Paper One - Regulatory Framework for Standard 2.9.4 (CP1) (FSANZ, 2023), FSANZ sought comment on most aspects of Standard 2.9.4 including definitions within the Code, overarching compositional considerations, labelling and the positioning of electrolyte drinks, as well as data on the current sports foods market.

1.3 Purpose of this consultation paper

FSANZ is seeking stakeholder views on the regulation of nutrition content and health claims for sports foods in Australia and New Zealand.

The scope of this paper is limited to the regulation of nutrition content and health claims for sports foods in the Code. Changes to current requirements under Standard 1.2.7 – Nutrition, health and related claims as they apply to foods other than sports foods are out of scope for P1010.

FSANZ has not proposed any approaches to the regulation of sports foods in this consultation paper. Instead, we are seeking stakeholder views which will be considered in the 1st CFS, in line with the FSANZ Act objectives.

1.4 Previous relevant FSANZ proposals

1.4.1 Proposal P236 – Sports Foods

A review of Standard 2.9.4 began in 2001 during the transition to the joint Code, under Proposal P236 - Sports Foods.³ The Initial Assessment was released for public consultation

¹ Department of Health. August 2018: Sports Supplements Roundtable: Report on Discussions and Next Steps. Accessible at: <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/sports-sup-roundtable>.

² Call for data on substances used in contemporary sports foods: <https://www.foodstandards.gov.au/code/changes/Pages/Call-for-data-on-substances-used-in-contemporary-sports-foods.aspx>.

³ Proposal P236: <https://www.foodstandards.gov.au/code/proposals/Pages/proposalp236sportsfo1143.aspx>.

in August 2001. P236 was formally abandoned in 2013, following a decision to prepare a new proposal (P1010) to enable full consideration of all issues, including those raised at Initial Assessment, under FSANZ's current legislative framework and regulatory process.⁴

1.4.2 Proposal P293 – Nutrition, Health and Related Claims

Coinciding with P236, Standard 1.2.7 was developed under Proposal P293 – Nutrition, Health and Related Claims⁵ in response to the endorsement by the Food Ministers' Meeting (then the Ministerial Forum on Food Regulation) of the Policy Guideline on Nutrition, Health and Related Claims in 2003 (refer Section 2.1.2). P293 included extensive stakeholder consultation from 2004 to 2012, and Standard 1.2.7 was gazetted in 2013.

P293 aimed to address a number of problems including:

- restrictions on adequate information about nutrition and health related aspects of foods for consumers at point of sale and in advertisements for food to enable them to make informed food choices; and
- the potential for misleading or deceptive conduct relating to nutrition and health claims on food labels and in food advertising.

The nutrition profiling scoring criterion (NPSC) was developed under P293 to determine the eligibility of foods for making health claims according to their nutrient profile. Under P293 it was not considered appropriate for special purpose foods (including sports foods) to be required to meet the NPSC. The rationale for this exemption was that these foods are specifically formulated for specific dietary purposes such as for the specific needs of infants, a supplement to the normal diet, or to aid with sports performance.⁶ Foods standardised under Standards 2.9.2, 2.9.3 and, depending on the product type, Standard 2.9.4, must meet certain compositional requirements prescribed under the Part 2.9 standards⁷. It was therefore not considered appropriate for these foods to also be required to meet the NPSC that was developed for general purpose foods.

Under P293 it was recommended that the permissions for nutrition, health and related claims for sports foods be addressed by the review of Standard 2.9.4, and that if the generic provisions for claims as provided by Standard 1.2.7 are not considered suitable, specific provisions around claims for sports foods could be provided and these would override Standard 1.2.7.⁸

1.4.2.1 Step up approach to regulation of nutrition and health claims

Standard 1.2.7 incorporates a step up approach to regulation, meaning increasing regulation depending on the type of claim from nutrition content claims to general level health claims (GLHCs) to high level health claims (HLHCs). This was founded on the principle that regulatory intervention is warranted where there is a potential for consumers to be misled. It is also described in the Policy Guideline on Nutrition, Health and Related Claims i.e. that

⁴ P236 Draft Assessment Report (Abandonment) 2013:

<https://www.foodstandards.gov.au/code/proposals/Documents/P236-SportsFoods-DAR.pdf>.

⁵ P293 – Nutrition, Health and Related

Claims: <https://www.foodstandards.gov.au/code/proposals/pages/proposalp293nutritionhealthandrelatedclaims/Default.aspx>.

⁶ P293 FAR Attachment 6 General Level Health Claims:

<https://www.foodstandards.gov.au/code/proposals/Documents/P293%20Health%20Claims%20FAR%20Attach%2006%20FINAL.pdf>.

⁷ Standard 2.9.5 – Foods for special medical purposes was gazetted post Standard 1.2.7.

⁸ P293 - Preliminary Final Assessment Report:

[https://www.foodstandards.gov.au/code/proposals/documents/P293%20Health%20claims%20PFAR%20+%20Attach%201%20FINAL%20\(2\).DOC](https://www.foodstandards.gov.au/code/proposals/documents/P293%20Health%20claims%20PFAR%20+%20Attach%201%20FINAL%20(2).DOC).

claims offering a higher ‘degree of promise’ to the consumer should be more highly regulated.

General requirements apply to all nutrition content claims and health claims irrespective of their classification and specific requirements apply according to the classification of the claim (i.e. food vehicle eligibility criteria, substantiation and wording conditions). These requirements apply generally to most foods, however there are some exceptions for certain foods, including sports foods (see Section 4).

Elements of the step up approach are summarised below, and illustrated in Figure 1.

- Nutrition content claims and health claims about certain nutrients are subject to specific qualifying criteria. This ensures a minimum or maximum amount of the claimed property in the food, and for some claims, specific disqualifying criteria in relation to certain nutrients e.g. the saturated fat content is included in the conditions for cholesterol claims.
- The nutrient profiling scoring criterion (NPSC) determines the eligibility of foods for making health claims according to their nutrient profile. The NPSC assesses the overall nutritional profile of the food and is underpinned by national nutritional guidelines.
- Unlike GLHCs, which can be based on self-substantiated food-health relationships (FHRs), FHRs that underpin HLHCs are required to be pre-market assessed and approved by FSANZ.

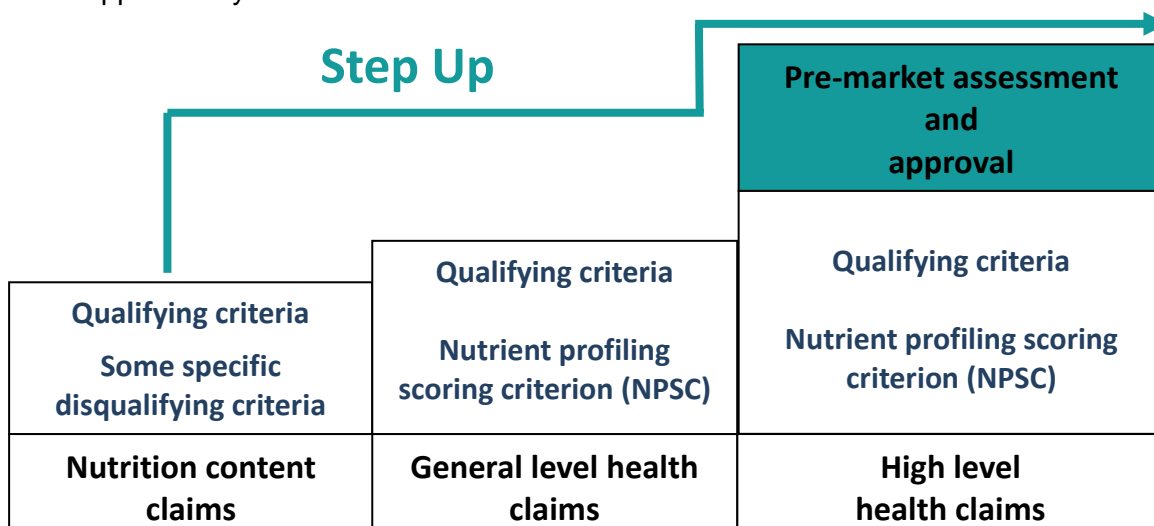


Figure 1: Step approach to regulation of nutrition content and health claims

1.4.3 Proposal P1030 - Composition and Labelling of Electrolyte Drinks

Proposal P1030⁹ was originally prepared in 2014 after gazettal of Standard 1.2.7. Under P1030, FSANZ initially sought to deliver an interim approach for sports foods and electrolyte drinks (EDs) pending the future review of Standard 2.9.4 to:

- Permit sports foods and EDs to carry health claims consistent with their respective intended purpose and in accordance with Standard 1.2.7 – Nutrition, health and related claims.
- Transfer the regulation of EDs from Standard 2.6.2 – Non-alcoholic beverages and brewed soft drinks to Standard 2.9.4 – Formulated supplementary sports foods.

⁹ P1030 - Composition and labelling of electrolyte drinks:
<https://www.foodstandards.gov.au/code/proposals/Pages/P1030CompositionandlabellingofElectrolyteDrinks.aspx>.

- Retain the existing claims permitted in the Code for sports foods and EDs. Consistent with the current provisions for special purpose foods, sports foods and EDs carrying such claims would not have to meet the NPSC.

FSANZ issued a CFS in 2014, which received mixed support from stakeholders. Some stakeholders supported the proposed approach or elements of the proposed approach, whereas others did not. A number of submitters raised concern that permitting more health claims on sports foods and EDs without the requirement to meet the NPSC would give them a ‘health halo’, promoting consumption of these foods inconsistent with national nutrition guidelines.

In 2021, the scope of the proposal was revised to only consider the composition and labelling of EDs and a supplementary consultation paper released to seek further views. At this time, P1010 had also been prepared which would now capture the review of sports foods intended under P1030.

A draft variation to Standard 2.6.2 – Non-alcoholic beverages and brewed soft drinks was gazetted in August 2022.

Under P1030, FSANZ committed to considering whether to transfer the regulation of EDs from Standard 2.6.2 to Standard 2.9.4 as part of P1010.

2 Background

2.1 Australia New Zealand Food Regulation Ministerial Policy Guidelines

FSANZ must also have regard to guidelines developed by the Food Ministers’ Meeting in reviewing, developing and varying standards in the Code. Two policy guidelines are relevant for the purposes of this consultation paper.

2.1.1 Policy Guideline on the Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods

The Policy Guideline on the Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods¹⁰ distinguishes between special purpose foods covered by Part 2.9 of the Code and other food regulated elsewhere in the Code, and includes the Policy Principle that:

- 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 who the special purpose food is not intended.

The target population for special purpose foods is specified 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

¹⁰ Policy Guideline on the Intent of Part 2.9 of the Food Standards Code - Special Purpose Foods: <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-Intent-of-Part-2-9-of-the-Food-Standards-Code-Special-Purpose-Foods>.

- physical and physiological conditions that require altered energy intake; that occasion the use of special purpose food’.

The Policy Guideline notes that guidance in relation to nutrition, health and related claims on special purpose foods is covered by the Policy Guideline on Nutrition, Health and related claims.

2.1.2 Policy Guideline on Nutrition, Health and Related Claims

The Policy Guideline on Nutrition, Health and Related Claims¹¹ sets out the policy principles underpinning the regulation of nutrition content and health claims and aims to permit claims and encourage industry to innovate whilst ensuring consumers are not misled. This includes overarching Policy Principles, claim pre-requisites, and the claims classification framework that sets out the criteria for nutrition content claims, general level health claims and high level health claims.

2.2 Current Code requirements

2.2.1 Standard 1.2.7 – Nutrition, health and related claims

Nutrition content claims, health claims and endorsements are voluntary statements made by a food business about the content of certain nutrients or substances in a food, or the relationship between food and health. Standard 1.2.7 and Schedules 4, 5 and 6 of the Code set out the conditions under which such claims can be made about food in Australia and New Zealand. This includes:

- the claims that may be made on labels or in advertisements about the nutritional content of food (described as ‘nutrition content claims’); and
- the claims that may be made on labels or in advertisements about the relationship between a food or a property of a food, and a health effect (described as ‘health claims’); and
- a description of the conditions under which such claims may be made; and
- a description of the circumstances in which endorsements may be provided on labels or in advertisements.

Standard 1.2.7 includes the conditions for nutrition content claims¹², general level health claims¹³ (GLHCs), high level health claims¹⁴ (HLHCs), and endorsements. Claims that are therapeutic¹⁵ in nature are not permitted (section 1.2.7—8).

Schedule 4 – Nutrition, health and related claims includes over 200 pre-approved food-health relationships (FHRs) for GLHCs and 13 pre-approved FHRs for HLHCs, and their conditions of use. GLHCs can also be made based on self-substantiated FHRs by following the process for systematic review outlined in Schedule 6 - Required elements of a systematic review.

¹¹ Policy Guideline on Nutrition, Health and Related Claims:
<https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-Nutrition-Health-and-Related-Claims>.

¹² Means a claim that is about the presence or absence of biologically active substance, dietary fibre, energy, minerals, potassium, protein, carbohydrate, fat, the components of any one of protein, carbohydrate or fat, salt, sodium, vitamins or glycaemic index or glycaemic load; and does not refer to the presence or absence of alcohol; and is not a health claim.

¹³ General level health claim means a health claim that is not a high level health claim.

¹⁴ High level health claim means a health claim that refers to a serious disease or a biomarker of a serious disease.

¹⁵ A claim that refers to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or compare a food with a food that is represented in any way to be for therapeutic use; or likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason.

When making a health claim, a dietary context statement must be included with the claim¹⁶ (paragraph 1.2.7—20(3)(a)). The dietary context statement must state that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods and must be appropriate for the claim being made. If the food-health relationship (FHR) is listed in Schedule 4, words with the same meaning as the relevant dietary context statement in column 4 of Schedule 4 (paragraph 1.2.7—20(6)(c)) must be included together with the health claim (subsection 1.2.7—20(6)). If the FHR is established by systematic review the dietary context statement must be consistent with the conclusions of the systematic review (paragraph 1.2.7—20(6)(c)).

Standard 1.2.7 includes the requirement for a food to meet the nutrient profiling scoring criterion (NPSC)¹⁷ to be eligible to carry a health claim. The NPSC applies generally to most foods carrying health claims however some specific exemptions apply. In accordance with paragraph 1.2.7—18(4), special purpose foods standardised under Part 2.9 (including sports foods) do not need to meet the NPSC to make a health claim. The method for determining the NPSC is outlined in Schedule 5 – Nutrient profiling scoring method.

Standard 1.2.7 applies to most food including sports foods, however Standard 1.2.7 does not apply to claims expressly permitted elsewhere in the Code (paragraph 1.2.7—6(a)), such as those permitted for sports foods in Division 3 of Standard 2.9.4 (refer Table 1 in Section 2.2.3).

Division 6 of Standard 1.2.7 describes the circumstances in which endorsements may be provided on labels or in advertisements. An endorsement is a nutrition content claim or health that made with the permission of an endorsing body.

2.2.2 Standard 1.2.8 – Nutrition information requirements

Section 1.2.8—5 of Standard 1.2.8 requires most packaged food¹⁸, including sports foods to be labelled with a nutrition information panel (NIP). Sections 1.2.8—6 and 1.2.8—7 set out the requirements for what information must be included and how to express that information in a NIP. This includes the declaration of the average quantity of energy content, protein, fat, saturated fat, carbohydrate, sugars and sodium for a serving and a unit quantity of the food. Unless the Code otherwise provides, a NIP must be set out in the format in section S12—2 (subsection 1.2.8—6(2)).

If a claim requiring nutrition information¹⁹ 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)). In most cases, unless the Code otherwise provides, information provided voluntarily in a NIP constitutes a nutrition content claim (subsection 1.1.2—9(3)).

¹⁶ A dietary context statement does not need to be included on the label of a small package (subsection 1.2.7—20(4)).

¹⁷ Overview of the NPSC: <https://www.foodstandards.gov.au/industry/labelling/Pages/Consumer-guide-to-NPSC.aspx>.

¹⁸ Unless a food in a small package or otherwise exempt in accordance with subsection 1.2.8—5(2).

¹⁹ *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.

2.2.3 Standard 2.9.4 – Formulated supplementary sports foods

Standard 2.9.4 regulates the composition and labelling of formulated supplementary sports foods which are currently defined in the Code as foods or a mixture of foods *specifically formulated to assist sports people in achieving nutritional or performance goals*.

Division 2 – Formulated supplementary sports foods generally regulates the composition and labelling of all sports foods. In accordance with section 2.9.4—4 the label of a sports food is required to include the prescribed name 'formulated supplementary sports food', directions concerning its use and consumption, and various required statements.²⁰

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 sports foods, 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.

Division 3 – Particular formulated supplementary sports foods permits sports foods that meet one of three types of compositional specifications (high carbohydrate; protein energy; or energy) to carry statements on their labels. A summary of Division 3 statements and associated compositional criteria is provided in the table below.

Table 1: Labelling statements for particular formulated supplementary sports foods (Standard 2.9.4, Division 3)

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

²⁰ The prescribed name and labelling statements for sports foods are being reviewed under P1010.

	(c) not more than 70% of the average energy content of the product is derived from carbohydrate.		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 gastrointestinal 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 food and should be used for special fat loading strategies rather than everyday use.	(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.

2.3 Australian and New Zealand Regulations

2.3.1 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.

2.3.2 Therapeutic goods and supplemented food

Products intended to assist sport performance 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 1989²¹ (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.

²¹ Therapeutics Goods Act 1989: <https://www.legislation.gov.au/Details/C2021C00376>.

The Therapeutic Goods Administration (TGA) has recently 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').²² The declaration came into effect on 30 November 2020 and provides that goods that are represented as being for the improvement or maintenance of physical or mental performance in sport, exercise and recreational activity that meet certain criteria are 'therapeutic goods' and subject to regulation under the TG Act. This includes goods which are used, advertised or presented for gaining muscle, increasing mental focus, and increasing stamina. However, a product making claims relating to sport is not automatically a therapeutic good. The TGA states on its webpage²³ that, *it is accepted that there is some overlap between therapeutic indications that medicines can make and health claims that foods can make. The intent of the declaration is not to stop foods making health claims relating to sports performance. Rather, it is clarifying that products that make claims (therapeutic indications) relating to sport **and** contain medicinal type ingredients **and/or** are presented as medicine are appropriately regulated under the regulatory framework for medicines.*

A detailed description of the section 7 declaration and criteria is provided in Section 2.2.8 of CP1 (FSANZ, 2023).

In New Zealand, the *Dietary Supplements Regulations 1985*²⁴ applies to therapeutic sports supplements but excludes food-type dietary supplements. Some sports supplements may be regulated under the New Zealand Supplemented Food (Supplemented Food) Standard²⁵ (SFS) as a supplemented food. The SFS allows supplemented foods to make nutrition and health claims, including self-substantiated health claims in accordance with Standard 1.2.7 of the Code. Under the Trans-Tasman Mutual Recognition Arrangement (TTMRA), supplemented foods that can legally be sold in New Zealand, can be imported into and sold in Australia. The Supplemented Food Standard User Guide²⁶, developed by the New Zealand Ministry for Primary Industries, includes a flowchart to help determine whether a product is a food, dietary supplement or supplemented food. For more information on the TTMRA refer to Section 2.2.7 of CP1 (FSANZ, 2023).

Attachment A provides an overview of the relevant legislation for regulation of sports foods, supplements and therapeutic goods in Australia and New Zealand, and a comparison of the current permissions for nutrition and health claims on these products.

2.3.3 Fair trading laws

The above regulations work in conjunction with requirements in consumer protection legislation in Australia and New Zealand which prohibit misleading or deceptive conduct, and false or misleading representations about goods and services. In Australia, the Australian Competition and Consumer Commission (ACCC) enforces the *Competition and Consumer Act 2010* (Cth) and States and Territories enforce their own consumer protection legislation. In New Zealand, the New Zealand Commerce Commission (NZCC) enforces the *Fair Trading Act 1986* (NZ) which prohibits false and misleading conduct by businesses.

²² Therapeutic Goods (Declared Goods) Order 2019: <https://www.legislation.gov.au/Series/F2019L01352>.

²³ Frequently asked questions: Sports supplements section 7 declaration: <https://www.tga.gov.au/resources/resource/guidance/frequently-asked-questions-sports-supplements-section-7-declaration>.

²⁴ Dietary Supplement Regulations 1985: https://www.legislation.govt.nz/regulation/public/1985/0208/latest/DLM102109.html?search=ts_regulation_regulations+1985_resel&p=1&sr=1.

²⁵ New Zealand Food (Supplemented Food) Standard: <https://www.mpi.govt.nz/dmsdocument/11365-New-Zealand-Food-Supplemented-Food-Standard-2016>.

²⁶ Supplemented Food Standard User Guide: <https://www.mpi.govt.nz/dmsdocument/13092-Supplemented-food-standard-user-guide>.

2.4 International regulations

In developing food regulatory measures, FSANZ must have regard to, among other things, the promotion of consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry.

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.

Several countries have specific regulations on the addition of substances such as vitamins and minerals, as well as regulations on labelling and claims made on such products to the effect that they must not be misleading.

2.4.1 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 World Health Organization (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 may be relevant to sports foods. The Codex Guidelines for Vitamin and Mineral Food Supplements²⁷ covers supplements in forms such as capsules, tablets, powders, and solutions. The Guidelines align the labelling requirements for vitamin and mineral food supplements with other Codex labelling requirements including the General Guidelines on Claims (CAC/GL 1-1997)²⁸ and the Codex Guidelines for Use of Nutrition and Health Claims.²⁹

2.4.2 European Union

In the European Union (EU) foods intended for sports people are considered as 'foods for normal consumption' (rather than sports-specific foods) (European Commission, 2016), and must comply with general food laws including nutrition and health claims labelling.³⁰

In the EU only pre-approved nutrition and health claims are permitted on foods. A public EU Register of Nutrition and Health Claims³¹ lists all permitted nutrition claims and all authorised and non-authorised health claims and their conditions of use.

FSANZ previously considered EU claims under P293 (refer Section 1.4.2), where a number of EU claims were adopted for inclusion in Schedule 4 of the Code.³² Those EU claims adopted as FHRs in Schedule 4 are applicable to general purpose foods, and are not specific to sports foods.

²⁷ Guideline for Vitamin and Mineral Food Supplements (CAC/GL – 55 – 2005):

https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B55-2005%252Fcxg_055e.pdf.

²⁸ General Guidelines on Claims (CAC/GL 1-1979): https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B1-1979%252FCXG_001e.pdf.

²⁹ Guidelines for Use of Nutrition and Health Claims <http://www.fao.org/ag/humannutrition/32444-09f5545b8abe9a0c3baf01a4502ac36e4.pdf>.

³⁰ Regulation (EC) No 1924/2006: <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32006R1924>

³¹ EU Register of Health Claims: https://food.ec.europa.eu/safety/labelling-and-nutrition/nutrition-and-health-claims/eu-register-health-claims_en.

³² P293 - Review Report SD9 Consideration of EU approved health claims: https://www.foodstandards.gov.au/code/proposals/documents/P293_SD9.pdf.

EU authorised health claims specific to sport and physical performance are listed in Attachment B. This list was determined from a keyword search of the EU register using the terms 'physical', 'performance', 'exercise' and 'muscle'. Health claims which contribute to 'normal' physiological function have not been included e.g. contributes to normal muscle function (calcium, magnesium, potassium, vitamin D), contributes to normal mental performance (pantothenic acid). Nutrition claims have not been included.

The EU health claims that relate to physical performance that have not been considered by FSANZ previously are:

- Carbohydrate solutions contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise in trained adults.
- Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle.
- Daily creatine consumption can enhance the effect of resistance training on muscle strength in adults over the age of 55.

The following additional EU health claim relating to creatine was considered previously by FSANZ under P293 however, was not included due to the existing prohibition in Standard 2.9.4 on claims about performance on a sports food³³:

- Creatine increases physical performance in successive bursts of short-term, high intensity exercise.

Two further EU authorised claims were considered under P1030, where three health claims, adopted from the EU claims for carbohydrate electrolyte solutions for hydration, for rehydration, and hydration to maintain performance were permitted for use on electrolyte drinks (refer Section 1.4.3).

2.4.3 United States

Some 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 United States. Among the claims that can be used on food and dietary supplement labels are three categories of claims: nutrient content claims, structure/function claims, and health claims.

Nutrient content claims that describe the level of a nutrient in a food are permitted if they have been authorised by Food and Drug Administration (FDA) and are made in accordance with the FDA's authorising regulations.

Structure/function claims describe the role of a nutrient or ingredient on the structure or function of the human body, and may appear on the labels of food, dietary supplements, or drugs. The *Dietary Supplement Health and Education Act of 1994* (DSHEA) established some special regulatory requirements and procedures for using structure/function claims and two related types of claims on dietary supplements. Structure/function claims applied to dietary supplements are regulated by the FDA and products carrying them are required to have a specific disclaimer as well as be notified to the FDA. The disclaimer must also state that the dietary supplement product is not intended to diagnose, treat, cure, or prevent any disease, because only a drug can legally make such a claim. Manufacturers are responsible for making sure that their supplements are safe and that the claims on the product labels are truthful and not misleading. The FDA does not require conventional food manufacturers to

³³ P293 - Review Report SD9 Consideration of EU approved health claims:
https://www.foodstandards.gov.au/code/proposals/documents/P293_SD9.pdf

notify FDA about their structure/function claims, and disclaimers are not required for claims on conventional foods, however such claims are required to be truthful and not misleading.

Health claims describe the relationship between a food substance (a food, food component, or dietary supplement ingredient) and reduced risk of disease or health related condition. Health claims are required to be reviewed and evaluated by the FDA prior to use. To be approved as an authorised health claim, there must be significant scientific agreement among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship. Qualified health claims are supported by some scientific evidence, but do not meet the significant scientific agreement standard and must be accompanied by a disclaimer or other qualifying language to accurately communicate the level of scientific evidence supporting the claim.

2.4.4 Canada

In Canada, sports foods can be regulated as a food, supplemented food, or natural health product (NHP). NHPs are a category of drug and are regulated under the *Natural Health Products Regulations*³⁴ and must have a product license to be sold in Canada. The product licence sets out the recommended use or purpose authorised for the product. NHPs may only display the recommended use(s) or purpose(s) using the exact wording (also referred to as 'indications for use'), as expressed in the market authorisation.

The federal government finalised amendments to the *Food and Drug Regulations (FDR)*³⁵ in July 2022 which introduced a new regulatory framework for supplemented foods (the Supplemented Foods Framework). Supplemented foods are subject to existing labelling requirements as for pre-packaged foods under the FDR, in addition to labelling requirements specific to supplemented foods. Health claims are restricted on products that contain certain supplemental ingredients. For example, claims related to vitamins, minerals, hydration and electrolyte replacement, and physical performance are restricted on certain supplemented foods that contain caffeine as a supplemental ingredient.

In accordance with section 3 of the *Food and Drugs Act*³⁶ claims, express or implied, related to diseases and health conditions listed in Schedule A.1 of the Food and Drugs Act are prohibited on foods, including supplemented foods, unless already permitted in the FDR. Such claims are subject to pre-market assessment and health claims that have been reviewed and accepted will be added to the list of accepted claims.³⁷

Pre-market approval is voluntary for health claims on food products, including function claims and claims about disease risk reduction claims diseases or health conditions not listed in Schedule A.1 of the *Food and Drugs Act*. For any claims that have not been reviewed and accepted by Health Canada, food manufacturers and distributors must disclose the evidence supporting these claims upon request from the Canadian Food Inspection Agency.

³⁴ Natural Health Products Regulations: <https://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/>

³⁵ Food and Drug Regulations: <https://laws-lois.justice.gc.ca/eng/regulations/C.R.C., c. 870/page-1.html>.

³⁶ Food and Drugs Act <https://laws-lois.justice.gc.ca/eng/acts/f-27/index.html>.

³⁷ Health Claim Assessments: <https://www.canada.ca/en/health-canada/services/food-nutrition/food-labelling/health-claims/assessments.html>.

3 Relevant Considerations

3.1 Consumer research

This section summarises available research regarding consumer motivations for using sports foods, as well as consumer value, use and perceptions of claims and other labelling information on sports foods. Only Australian and New Zealand based studies are considered, given that international sports food regulatory environments and markets differ from that of Australia and New Zealand. Overall, there is limited research available on consumer perceptions of nutrition content or health claims on sports foods.

The following provides an overview of key findings:

- Athletes primarily use sports foods to enhance energy and performance, therefore performance related claims on sports foods align with athletes' current motivations for consuming them.
- No study has directly examined whether athletes value claims on sports foods.
- Consumers from the broader population (non-elite physically active and sedentary consumers) do not seem to value on-label claims, but this information may still indirectly influence their consumption of sports foods if their trusted sources (e.g. gym instructors/coaches) rely on such claims.
- Consumers (both athletes and the broader population) are likely to believe that claims on sports foods are scientifically supported.
- It is unclear whether the presence of a claim on sports foods misleads consumers into mistakenly perceiving the product as healthy.

A more detailed description of the available consumer research is outlined below.

3.1.1 Consumer motivations for using sports foods

Athletes primarily use sports foods to enhance energy and performance, consistent with their intended purpose (Clancy, 2020; Pumba, 2007; Shaw, 2012; Whitehouse & Lawlis, 2017). Therefore performance-related claims on sports foods align with athletes' current motivations for consuming them.

Motivations for consuming sports foods within the broader population are more varied, with reasons including performance enhancement, as well as reasons that are inconsistent with their intended purpose, such as snacking outside of an exercise-related context (Colmar, Brunton, 2010; FSANZ, 2013). It is unclear whether removing performance-related claims on sports foods would further encourage inappropriate use of sports foods among sedentary consumers.

3.1.2 Consumer value and use of claims (and other labelling information) on sports foods

Few studies have directly examined the importance of labelling information on sports foods for athletes. One available study indicates that elite swimmers may frequently read the label of sports foods before consuming them (Shaw, 2013). However, participants in this study were not asked about the importance of specific types of information (such as claims) on the label.

Within the broader population (both non-elite physically active and sedentary people), product labels are the most common information source that people are exposed to regarding the risks and benefits of sports foods (reported by up to 72% of people). However,

only a subset of people (up to 12%) report that product labels are an information source that *influences* their decision to consume sports foods (FSANZ, 2013). Furthermore, claims³⁸ on the labels of sports foods are not seen as important by physically active consumers, as products are already perceived as credible due to recommendations from coaches/gym instructors (Colmar Brunton, 2010). It is unclear whether claims on sports foods labels are influential sources of information for coaches/gym instructors. For sedentary consumers, the nutrition information panel is used to compare the protein, fat and energy content across different products; front labels are only looked at for flavour information (Colmar Brunton, 2010).

3.1.3 Consumer perceptions of claims on sports foods

Consumers (both athletes and the broader population) are likely to believe that claims about sports foods are scientifically supported, simply because they believe that untrue claims and/or harmful products would not be allowed to exist within the Australian and New Zealand food system (Colmar Brunton, 2010; Shaw, 2013). Furthermore, consumers report having faith in scientific claims that are visible on the front of the label of sports drinks (Colmar Brunton, 2010); this is likely the same for sports foods.

Consumers from the broader population generally perceive sports foods to be healthy when consumed in moderation (Colmar Brunton, 2010). However, it is unclear whether this is related to the presence of nutrition content or health claims. FSANZ is unaware of any research that has directly examined the effect of nutrition content or health claims on consumers' perceptions of sports foods.

3.1.4 Question

Q1. Are you aware of any additional, relevant consumer evidence about consumer perceptions of nutrition content or health claims on sports foods? [yes/no]. If yes, please provide details.

3.2 Market research

An overview of the Australian, New Zealand and global markets was provided in Section 3.1 of CP1 (FSANZ, 2023). FSANZ recognises that much of the available market data is outdated and sought data from stakeholders of the current sports food market through questions in CP1.

A recently published study reported results from an audit undertaken in 2021 on the labelling of formulated supplementary sports food products in Australia (Chapple et al., 2023). The audit initially collected data from 558 products resembling sports foods for retail sale throughout Melbourne, Victoria. Products included in the audit (n=275) were labelled with either the prescribed name, 'formulated supplementary sports food', or the warning and advisory statements as required by Standard 2.9.4³⁹.

The study reported that all 275 products in the audit were labelled with multiple claims and grouped the claims into categories as defined by the authors. The study reported:

- 98.5% of products displayed 'nutrition content claims' e.g. high protein, 30g protein;

³⁸ In Colmar Brunton (2010) consumers talked about 'claims' in general – no further information was provided regarding the types of claims they were referring to (i.e., performance-related claims, nutrition-content claims, or both).

³⁹ Required labelling statements for sports foods are outlined in subsection 2.9.4—4(1).

- 65.1% of products displayed 'general level health claims' (nutrient and physiological function relationship) e.g. protein for increased muscle mass;
- 62.2% of products displayed 'sports effect claims' (effect of nutrient on sports participation or sports outcome);
- 52.7% of products displayed 'product quality claims' e.g. premium, high quality;
- No products displayed 'high level health claims' (nutrient and disease relationship).

Of the 184 products included for nutritional analysis, only nine products met the specific compositional categories outlined by Division 3 of Standard 2.9.4 (see Section 2.2.3). The number of products carrying labelling statements in accordance with Division 3 of Standard 2.9.4 was not reported.

3.2.1 Question

- Q2. For industry stakeholders: how many of your company's stock keeping units (SKUs) for formulated supplementary sports foods are labelled with the following:
- Nutrition content claims;
 - Health claims;
 - The Division 3 statements in Standard 2.9.4 for high carbohydrate supplement, protein energy supplement or energy supplement (refer Table 1 of Section 2.2.3).

3.3 Summary of submissions to consultation paper one

CP1 focused on the framework underpinning the regulation of sport foods in Australia and New Zealand. Under this consultation FSANZ sought views on various aspects of the regulation and on specific questions relevant to nutrition and health claims about sports foods as follows:

- Please discuss whether you think the existing labelling requirements for sports foods enable consumers to make informed choices. Please provide reasons for your view.
- 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.
- Have you identified issues on any other labelling aspects specific to sports foods? Please provide detail.
- 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?

A summary of submitter responses is provided in Attachment 3 and submissions are available on the FSANZ website⁴⁰.

Submitters who provided feedback on the usefulness of Division 3 statements were generally in agreement that they are not fit for purpose, being that they are:

- outdated and not reflective of current sports food market
- not aligned with sports nutrition research e.g. there is little research to support the use of protein-energy supplements during exercise
- vague and do not communicate a clear benefit or purpose of the product
- poorly utilised due to not many products meeting the compositional criteria.

A few submitters commented that Standard 1.2.7 should apply to sports foods as this would allow for claims to be made on sports foods to communicate their benefits to consumers,

⁴⁰ P1010 – Formulated Supplementary Sports Foods:
<https://www.foodstandards.gov.au/code/proposals/Pages/P1010.aspx>.

including those relating to beneficial physiological effects. One submitter commented that general purpose foods have permission to make general level health claims under Standard 1.2.7 about muscle building and repair, and energy production and release, however this is not permitted for sports foods under Standard 2.9.4. Given that sports foods are developed for sports people, submitters noted it would benefit consumers if they were permitted to make pre-approved health claims based on food-health relationships in Schedule 4, as well as self-substantiate health claims.

One submitter commented that applying Standard 1.2.7 to sports foods would help to future proof Standard 2.9.4 and support future innovation to keep pace with this evolution. Another submitter commented that clarity is required on the interpretation of 'restricted representations' as defined in section 2.9.4—7, and how this applies to claims under Standard 1.2.7 and Schedule 4 for sports foods.

Submitters identified special requirements that should be considered for sports foods if Standard 1.2.7 were to apply:

- How to manage sports foods that do not meet the NPSC.
- Integrating into Standard 1.2.7 a section specifically relating to sports performance claims.
- Standard 1.2.7 does not appear to have been created with sports foods in mind, so largely irrelevant, except for protein claims.

Three submitters were not in support of allowing self-substantiated health claims on sports foods and suggested that instead, consideration be given to limiting claims on sports foods to a list of pre-approved claims. One submitter had particular concern about permitting self-substantiated health claims on sports foods containing potentially novel foods or nutritive substances. It was commented that the approach to pre-approve claims is consistent with the European Commission's model, and the permitted claims in the EU could be leveraged as a starting point for pre-approved claims in the Code.

Two submitters raised concerns regarding the application of Standard 1.2.7 and potential reduced clarity at the food medicine interface in Australia, particularly if the already broad range of claims on sports foods were expanded. One submitter noted that claims about physiological effects, such as gaining muscle; increasing mental focus; increase metabolism; increasing stamina etc are covered in the Section 7 Therapeutic Goods (Declared Goods) Order 2019⁴¹ (also refer to Section 2.3.3 of this report for more detail on declarations under Section 7 of the TG Act).

Three submitters suggested applying the Australian Institute of Sport (AIS) Sport Supplement Framework⁴² in relation to the types of claims a sports food can make. This system ranks sports foods and supplement ingredients into four groups according to scientific evidence. For example, it was suggested that products that contain ingredients from 'Group A' should be able to claim that the sports food or supplement ingredient 'can support or enhance sports performance' in ways that align with AIS findings.

⁴¹ Therapeutic Goods (Declared Goods) Order 2019: <https://www.legislation.gov.au/Series/F2019L01352>.

⁴² The Australian Institute of Sport (AIS) Sport Supplement Framework <https://www.ais.gov.au/nutrition/supplements>

4 Framework for regulation of nutrition content and health claims on sports foods

Under P1010, FSANZ is considering the framework for regulating nutrition content and health claims about sports foods. This includes consideration of any specific requirements for sports foods and how these should be targeted for a specific population group.

Nutrition and health claims are one way of providing information to consumers to enable informed choice. For example, health claims describe the relationship between a food and a health effect on the human body, such as a physiological process/outcome, or physical performance. Such health effects relate directly to the purpose of sports foods, currently defined as being *specifically formulated to assist sports people in achieving specific nutritional or performance goals*.

There are varying provisions for making nutrition content and health claims about other special purpose foods in the Code. For example: infant formula products are not permitted to make nutrition content or health claims (paragraph 1.2.7—4(b)) whereas formulated meal replacements and formulated supplementary foods can make nutrition content and health claims in accordance with Standard 1.2.7, although some specific requirements outlined in Standard 2.9.3 apply for vitamin and mineral nutrition content claims. As for most foods, the requirements of Standard 1.2.7 apply to sports foods. In addition to those provisions, specific requirements for sports foods are outlined in Standard 2.9.4.

Sports foods are subject to the generic requirements as outlined in Division 3 (Claims framework and general principles) of Standard 1.2.7, including:

- Standard 1.2.7 does not apply to certain foods including a food intended for further processing, packaging or labelling prior to retail sale.
- Standard 1.2.7 does not apply to certain claims or declarations that are expressly permitted by the Code.
- the form of the food to which the claim applies.
- Claims not to be therapeutic in nature.
- Claims not to compare vitamin or mineral content.
- Standard 1.2.7 does not prescribe words that must be used when making a claim.

The current provisions for nutrition content claims and health claims, including endorsements, about sports foods are discussed in the following sections.

4.1 Nutrition content claims

4.1.1 Current regulations

Nutrition content claims, by definition, are claims about the presence or absence of biologically active substance⁴³, dietary fibre, energy, minerals, potassium, protein, carbohydrate, fat, the components of any one of protein, carbohydrate or fat, salt, sodium, vitamins or glycaemic index or glycaemic load.

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

⁴³ biologically active substance means a substance, other than a nutrient, with which health effects are associated.

4.1.1.1 Standard 1.2.7

In accordance with section 1.2.7—12, nutrition content claims about properties of food in section S4—3 can be made about sports foods, providing the relevant conditions in Standard 1.2.7 and Schedule 4 are met. Nutrition content claims about vitamins or minerals (not including potassium and sodium) in section S4—3⁴⁴ are not permitted about sports foods under Schedule 4 however permission is provided for these claims in Standard 2.9.4 (see Section 4.1.1.2 below).

For properties of food not listed in section S4—3, a claim can only be made regarding the presence or absence of the property of food, or by specifying the amount of the property in the food (refer section 1.2.7—13).

Other general requirements for nutrition content claims in Standard 1.2.7 also apply to sports foods, including requirements for a statement about the form of the food (section 1.2.7—11), conditions for comparative claims (section 1.2.7—16) and implied slimming effects (section 1.2.7—15).

4.1.1.2 Standard 2.9.4

Specific requirements for nutrition content claims about vitamins and minerals and nutritive substances in Standard 2.9.4 apply to sports foods, and these are outlined below.

4.1.1.2.1 Vitamins and minerals

In accordance with section 2.9.4—6, the presence of vitamin and minerals in sports foods may be claimed 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% Recommended Dietary Intake (RDI) or Estimated Safe and Adequate Daily Dietary Intake (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.

For nutrition content claims about a vitamin or mineral the Code does not permit sports foods to use any other descriptors (e.g. good source), other than to claim the presence of the vitamin and mineral.

4.1.1.2.2 Nutritive substances

Section 2.9.4—5 requires that if the sports foods package includes a statement referring to the presence of a nutritive substance⁴⁵, the label must either state the amount of the nutritive substance by weight or list average quantity by weight⁴⁶; of the nutritive substance in the NIP.

⁴⁴ The entry in section 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.

⁴⁵ A substance is *used a nutritive substance* in relation to a food if it is added to the food to achieve a nutritional purpose.

⁴⁶ 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)).

4.1.2 Discussion

With the exception of vitamins and minerals, nutrition content claims about other properties of food in listed in Schedule 4 are permitted for sports food, providing the relevant conditions are met. This includes nutrition content claims about energy, macronutrients (e.g. protein, carbohydrate), dietary fibre, and cholesterol and use of specific descriptors in column 3 of section S4—3, such as ‘high’, ‘increased’ and ‘low’. For example, a nutrition content claim can be made that a sports food is a good source of protein if it contains at least 10 g of protein/serving.

For properties of food not listed in Schedule 4, a nutrition content claim on a sports food can only refer to the presence or absence or by specifying the amount of the property. This includes nutrition content claims about amino acids, caffeine and biologically active substances. Nutrition content claims that refer to the presence of a nutritive substance must include on the label the amount of the nutritive substance in accordance with section 2.9.4—5.

Specific requirements for vitamin and minerals nutrition content claims on sports foods are provided in Standard 2.9.4—6, and are limited to those which only refer to the presence of the vitamin or mineral. Other special purpose foods including foods for infants, formulated meal replacements, formulated supplementary food, and formulated supplementary food for young children are permitted to make ‘good source’ nutrition content claims, with specific provisions provided in the relevant Part 2.9 standards. However, a claim that a sports food is a good source of a vitamin or mineral is not currently permitted for sports foods under Standard 2.9.4, e.g. good source of vitamin C.

4.1.3 Questions

- Q3. Are there areas of concern regarding nutrition content claims on sports foods? [yes/no]. Please provide details.
- Q4. Should sports foods be permitted to make ‘good source’ nutrition content claims about vitamins and minerals? [yes/no]. Please provide reasons.
- Q5. Should nutrition content claims on sports foods be permitted in accordance with Standard 1.2.7? [yes/no]. Please provide reasons.
- Q6. Should any other specific provisions for nutrition content claims be considered for sports foods? [yes/no]. Please provide details.

4.2 Health claims

4.2.1 Current regulations

Health claim means *a claim which states, suggests or implies that a food or a property of food has, or may have, a health effect.*

Health effect means *an effect on the human body, including an effect on one or more of the following: a biochemical process or outcome; a physiological process or outcome; a functional process or outcome; growth and development; physical performance; mental performance; a disease, disorder or condition.*

Health claims about sports foods are regulated by Standard 1.2.7 and Standard 2.9.4.

4.2.1.1 Standard 1.2.7

Standard 1.2.7 sets out requirements for making general level health claims (GLHCs) and high level health claims (HLHCs) about food. Schedule 4 of the Code includes pre-approved food-health relationships (FHRs) for GLHCs and HLHCs. There are some pre-approved FHRs in Schedule 4 that may be of relevance to sports foods e.g. protein contributes to the growth of muscle mass.

Standard 1.2.7 also allows food businesses to self-substantiate FHRs for GLHCs by a process of systematic review as outlined in Schedule 6 of the Code. Standard 1.2.7 requires the person making the health claim to notify the Chief Executive Officer of FSANZ the details of the FHR that has been established by process of systematic review (paragraph 1.2.7—18(3)(b)).

In accordance with section 1.2.7—20, health claims made under Standard 1.2.7 must:

- state the food or property of food and the specific health effect; and
- include a statement of the population group in conjunction with the health claims if relevant; and
- include together with the health claim, a dietary context statement⁴⁷ and a statement of the form of the food⁴⁸ to which the health claim relates.

A summary of the provisions for health claims specific to sports foods under Standard 1.2.7 is provided below.

4.2.1.1.1 General level health claims

- GLHCs based on the pre-approved FHR in section S4—5 Code relating to folic acid and normal neural tube structure in the developing foetus are not permitted for sports foods.
- Under Standard 1.2.7, GLHCs about certain vitamins or minerals in section S4—5 include a condition that the food must meet the general conditions for making a nutrition content claim about the food or property of the food in section S4—3. As nutrition content claims about vitamins and minerals (not including potassium or sodium) are not permitted for sports foods under section S4—3, pre-approved GLHCs about these vitamins and minerals are not permitted for sports foods.
- Other GLHCs can be made about sports foods in accordance with the requirements of Standard 1.2.7 that do not relate to enhanced athletic performance or beneficial physiological effects (refer section 2.9.4—7).
- Under Standard 1.2.7, foods standardised under Part 2.9 (including sports foods) do not need to meet the NPSC to make GLHCs as is required for general purpose foods.

4.2.1.1.2 High level health claims

- HLHCs based on pre-approved FHRs in section S4—4 relating to folic acid and reduced risk of foetal neural tube defects are not permitted for sports foods.
- The pre-approved FHRs in section S4—4 relating to calcium and vitamin D includes a condition that the food must meet the general claim conditions for making a nutrition content claim about vitamin D in section S4—3. As nutrition content claims about vitamins and minerals (not including potassium or sodium) are not permitted for sports

⁴⁷ A dietary context statement need not be included on a label on a food for sale that is contained in a small package.

⁴⁸ If the form of the food to which the claim relates is the food as sold, the form of the food to which the claim relates need not be stated.

foods under section S4—3, HLHCs about calcium and vitamin D are not permitted for sport foods.

- Other pre-approved HLHCs can be made about sports foods in accordance with Standard 1.2.7.
- Under Standard 1.2.7, food standardised under Part 2.9 (including sports foods) do not need to meet the NPSC to make HLHCs as is required for general purpose foods.

4.2.1.2 Standard 2.9.4

Section 2.9.4—7 prohibits *representations in relation to enhanced athletic performance and beneficial physiological effects* on sports foods. An exception is provided for the labelling statements specified in Division 3, for sports foods that meet a prescribed composition for a high carbohydrate, protein-energy or energy supplement. If sports foods meet the composition criteria in Division 3, there are requirements for label statements that must or may be provided about their appropriate use and purpose (refer Table 1 of Section 2.2.3).

4.2.2 Discussion

Most foods are permitted to carry health claims, including claims about physical performance, providing certain claim criteria are met. However, apart from a few limited statements already permitted in Division 3 of Standard 2.9.4, sports foods are prohibited from *representations in relation to enhanced athletic performance and beneficial physiological effects*.

Some submitters to CP1 commented that the existing prohibition and current claim permissions for sports foods are overly restrictive and do not allow for the benefits of sports foods to be communicated to consumers (refer Section 3.3). A number of submitters also commented that the Division 3 statements are outdated, vague and poorly utilised by sports foods. While there is limited available research on how consumers perceive claims on sports foods, the literature shows that athletes primarily use these sports foods to enhance energy and performance (refer Section 3.1).

In the 2014 P1030 CFS, FSANZ proposed removing the prohibition in section 2.9.4—7 and permitting sports foods to carry health claims relating to their intended purpose in accordance with the requirements of Standard 1.2.7. By limiting health claims to the purpose of the food only, this approach aimed to reduce the potential for consumers to be misled as to the overall healthiness and purpose of sports foods. It was also noted that Standard 1.2.7 includes requirements to mitigate the possibility of consumers being misled by health claims - qualifying criteria for foods carrying health claims⁴⁹, the need for all health claims to be scientifically substantiated and requirements for dietary context statements to be made in association with health claims.

Some submitters to CP1 indicated their preference for health claims for sports foods to be limited to a list of pre-approved claims, and to not allow self-substantiated GLHCs on sports foods. It was suggested that claims permitted in the EU could be used as a starting point to determine appropriate pre-approved health claims for sports foods (refer Section 2.4.2 and Attachment B).

Of additional relevance is the exemption for sports foods to meet the NPSC to make a health claim (refer subsection 1.2.7—18(4)). As discussed in Section 1.4.2, during the development

⁴⁹ Qualifying criteria includes conditions for making nutrition content claims and health claims as specified in Schedule 4. For example, to make a general level health claim about protein and growth of muscle mass in accordance with S—5, the food must meet the general conditions for making a nutrition content claim about protein.

of Standard 1.2.7 it was not considered appropriate for special purpose foods (including sports foods) to be required to meet the NPSC as they are specifically formulated for specific dietary purposes. Under the current definition of sports foods, they are specifically formulated for specific dietary purposes and must meet certain prescribed compositional requirements related to those purposes. By the nature of their composition, many sports foods would not meet the NPSC. In CP1, one submitter noted that it would be important to ensure that sports foods are appropriately differentiated, to prevent other foods from being inappropriately categorised as sports foods to avoid the requirement to meet the NPSC.

Submitters to CP1 raised concerns regarding the restrictions on permissions for health claims about vitamins and minerals on sports foods. One submitter commented that sports foods are permitted to contain certain vitamins, minerals and nutritive substances which can have associated beneficial effects, and some of relevance are described in Schedule 4 e.g. Magnesium contributes to a reduction of tiredness and fatigue.

In the 2014 P1030 CFS FSANZ proposed an additional amendment to section S4—3 (then Schedule 1⁵⁰) to provide the general claim conditions that must be met for making a nutrition content claim about specific vitamins and minerals in relation to sports foods. The amendment would have allowed sports foods to make pre-approved health claims about specific vitamins and minerals listed in section S4—5 where the conditions specify that ‘the food must meet the general claim conditions for making a nutrition content claim’ about that vitamin and mineral. As discussed in Section 1.4.3 above, the scope of P1030 was revised in 2021 to only include electrolyte drinks, with sports foods to be considered under P1010.

4.2.3 Questions

- Q7. Should the prohibition in section 2.9.4—7 for representations on the label of sports foods in relation to enhanced athletic performance or beneficial physiological effects be retained? [yes/no]. Please provide reasons.
- Q8. If the prohibition in section 2.9.4—7 is removed, should sports foods be permitted to make health claims about enhanced athletic performance and/or beneficial physiological effects in accordance with Standard 1.2.7? [yes/no]. Please provide reasons.
- Q9. Should sports foods be permitted to make health claims that do not relate to enhanced athletic performance and/or beneficial physiological effects in accordance with Standard 1.2.7? [yes/no]. Please provide reasons.
- Q10. If the prohibition in section 2.9.4—7 is removed, are measures needed to ensure there is regulatory clarity between sports foods and therapeutic goods? [yes/no]. If yes, please provide details.
- Q11. Should sports foods be permitted to make high level health claims in accordance with Standard 1.2.7? [yes/no]. Please provide reasons.
- Q12. Sports foods are currently exempt from meeting the nutrient profiling scoring criterion (NPSC). Should this exemption be retained for sports foods? [yes/no]. Please provide details of circumstances when the NPSC should or should not apply.
- Q13. Should FSANZ consider including any authorised EU health claims as pre-approved health claims for sports foods (refer Attachment B)? [yes/no]. Please provide reasons.
- Q14. Do you support restricting health claims on sports foods to a list of pre-approved claims only? [yes/no]. Please provide reasons.
- Q15. Should any other specific provisions for health claims be considered for sports foods? [yes/no]. If yes, please provide details.

⁵⁰ The proposal P1025 Code Revision (completed in 2016) changed the structure of Standard 1.2.7 so that the requirements list Schedule 1 was moved to Schedule 4.

4.3 Endorsements

4.3.1 Current regulations

Endorsement means *a nutrition content claim or a health claim that is made with the permission of an endorsing body*. The requirements of Standard 1.2.7 do not apply to a claim in an endorsement if specific criteria under Division 6 of that Standard are met. An endorsement must not be therapeutic in nature (subsection 1.2.7—24(4)) or refer to a serious disease except in a reference to the endorsing body if the serious disease is part of the name of the endorsing body (subsection 1.2.7—24(3)).

The supplier of the food is required to have records demonstrating that the organisation that certified the endorsement is an endorsing body and these records must be made available upon request to the relevant authority (refer section 1.2.7—24), and the endorsing body must comply with the requirements of section 1.2.7—23.

4.3.2 Question

Q16. Should endorsements on sports foods be permitted in accordance with Standard 1.2.7? [yes/no]. Please provide reasons.
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5 Question summary

- Q1. Are you aware of any additional, relevant consumer evidence about consumer perceptions of nutrition content or health claims on sports foods? [yes/no]. If yes, please provide details.
- Q2. For industry stakeholders: how many of your company's stock keeping units (SKUs) for formulated supplementary sports foods are labelled with the following:
- Nutrition content claims;
 - Health claims;
 - The Division 3 statements in Standard 2.9.4 for high carbohydrate supplement, protein energy supplement or energy supplement (refer Table 1 of Section 2.2.3)
- Q3. Are there areas of concern regarding nutrition content claims on sports foods? [yes/no]. Please provide details.
- Q4. Should sports foods be permitted to make 'good source' nutrition content claims about vitamins and minerals? [yes/no]. Please provide reasons.
- Q5. Should nutrition content claims on sports foods be permitted in accordance with Standard 1.2.7? [yes/no]. Please provide reasons.
- Q6. Should any other specific provisions for nutrition content claims be considered for sports foods? [yes/no]. Please provide details.
- Q7. Should the prohibition in section 2.9.4—7 for representations on the label of sports foods in relation to enhanced athletic performance or beneficial physiological effects be retained? [yes/no]. Please provide reasons.
- Q8. If the prohibition in section 2.9.4—7 is removed, should sports foods be permitted to make health claims about enhanced athletic performance and/or beneficial physiological effects in accordance with Standard 1.2.7? [yes/no]. Please provide reasons.
- Q9. Should sports foods be permitted to make health claims that do not relate to enhanced athletic performance and/or beneficial physiological effects in accordance with Standard 1.2.7? [yes/no]. Please provide reasons.
- Q10. If the prohibition in section 2.9.4—7 is removed, are measures needed to ensure there is regulatory clarity between sports foods and therapeutic goods? [yes/no]. If yes, please provide details.
- Q11. Should sports foods be permitted to make high level health claims in accordance with Standard 1.2.7? [yes/no]. Please provide reasons.
- Q12. Sports foods are currently exempt from meeting the nutrient profiling scoring criterion (NPSC). Should this exemption be retained for sports foods? [yes/no]. Please provide details of circumstances when the NPSC should or should not apply.
- Q13. Should FSANZ consider including any authorised EU health claims as pre-approved health claims for sports foods (refer Attachment B)? [yes/no]. Please provide reasons.
- Q14. Do you support restricting health claims on sports foods to a list of pre-approved claims only? [yes/no]. Please provide reasons.
- Q15. Should any other specific provisions for health claims be considered for sports foods? [yes/no]. If yes, please provide details.
- Q16. Should endorsements on sports foods be permitted in accordance with Standard 1.2.7? [yes/no]. Please provide reasons.

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Attachment A: Comparison of nutrition content and health claims regulations for general food, sports food, and supplements and therapeutics in Australia and New Zealand

Name	General food	Formulated supplementary sports foods ¹	Supplemented food ² (New Zealand only)	Dietary supplements ³ (New Zealand only)	Therapeutic goods ⁴ (Australia only)
Applicable legislation for nutrition and health claims⁹	Australia New Zealand Food Standards Code	Australia New Zealand Food Standards Code	NZ Supplemented Food Standard 2016 and Australia New Zealand Food Standards Code	Dietary Supplements Regulations 1985 (under the Food Act 2014)	Therapeutic Goods Act 1989 and Therapeutic Goods Advertising Code
Relevant claims Standard(s)/ Section(s)	Australia New Zealand Food Standards Code Standard 1.2.7 and Schedule 4	Australia New Zealand Food Standards Code Standard 1.2.7, Schedule 4 and Standard 2.9.4	Australia New Zealand Food Standards Code Standard 1.2.7 and Schedule 4	Regulation 11 of Dietary Supplement Regulations	TGA advertising Code Section 9
Pre-approved health claims available?	Permissions and criteria in Australia New Zealand Food Standards Code Standard 1.2.7 and Schedule 4	Yes, as specified in Australia New Zealand Food Standards Code Standard 1.2.7 ⁶ , Schedule 4 and Standard 2.9.4 ⁷	Permissions and criteria in Australia New Zealand Food Standards Code Standard 1.2.7 and Schedule 4	No	Listed medicines must only use indications ⁸ that are pre-approved
Does the nutrient profile scoring criterion (NPSC) apply?	Must meet the NPSC before a health claim can be made.	Exempt	Must meet the NPSC before a health claim can be made.	N/A	N/A
Able to self-substantiate health claims?	Permitted for general level health claims only	Permitted for general level health claims only ⁷	Permitted for general level health claims only	Yes (not permitted to make therapeutic claims).	Listed medicines are limited to claims from the list of pre-approved permitted indications ⁸ . Registered and assessed listed medicines are assessed for efficacy prior to entering the market.

1. *A food or mixture of foods specifically formulated to assist sports people in achieving specific nutritional or performance goals.*
2. *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.*
3. *In general, dietary supplements are substance(s) for oral use that are packed in a controlled dosage form and are intended to supplement the intake of that substance(s) normally derived from food.*
4. *Two-tiered system for the regulation of medicines, which includes sports supplements marketed as medicines: 1. Registered medicines (higher risk) are assessed by the TGA for quality safety and efficacy, 2. Listed medicines (lower risk) are assessed by the TGA for quality and safety but not efficacy.*
5. *Fair trading laws in Australia and New Zealand require that labels do not misinform consumers through false, misleading, or deceptive representations. In Australia, this legislation includes the Australian Consumer Law contained in the Competition and Consumer Act 2010, and state and territory Fair Trading Acts and Food Acts. In New Zealand, this legislation includes the Food Act 2014 and Fair Trading Act 1986.*
6. *Standard 1.2.7 does not apply to a claim that is allowed by the Australia New Zealand Food Standards Code*
7. *Prohibited from making claims that relate to enhanced athletic performance or beneficial physiological effects (unless specific permission is given in Standard 2.9.4 Division 3).*
8. *Indications are statements that describe the specific therapeutic use for a medicine. They describe a medicine's claimed purpose or health benefit, for example: 'relieves coughs'. Indications can be specific (e.g. refer to a named non-serious condition); or non-specific (e.g. refer to general health maintenance).*

Attachment B: Authorised EU health claims relating to physical performance¹

FSANZ has determined this list from a keyword search of the EU register using the terms 'physical', 'performance', 'exercise' and 'muscle'. Health claims which contribute to 'normal' physiological function have not been included e.g. contributes to normal muscle function (calcium, magnesium, potassium, vitamin D), contributes to normal mental performance (pantothenic acid). Nutrition claims have not been included.

Nutrient, substance, food or food category	Claim	Conditions of use of the claim/Restrictions of use/Reasons for non-authorisation	Health relationship	Previously considered by FSANZ under P293	EFSA option reference/journal reference	Commission Regulation
Carbohydrate solutions	Carbohydrate solutions contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise in trained adults.	The claim may be used only for carbohydrate solutions which, according to the instructions of use, provide between 30 g and 90 g of carbohydrates/hour, where the carbohydrates in question are glucose, sucrose, fructose and/or maltodextrins, under the following conditions: a) Fructose (from fructose and/or sucrose) should not represent more than 1/3 of total carbohydrates, and b) Glucose (from glucose, sucrose and/or maltodextrins) should not exceed 60 g/h. Information shall be given to the consumer that the beneficial effect is obtained only by trained adults performing high-intensity (at least at 65 % of the VO ₂ max) and long-lasting (at least 60 min) physical exercise. The claim may be used only for foods intended for trained adults performing high-intensity and long-lasting physical exercise.	-	No	Q-2017-00621	Commission Regulation (EU) 2021/686 of 23/04/2021
Carbohydrate-electrolyte solutions	Carbohydrate-electrolyte solutions contribute to the maintenance of endurance performance during prolonged endurance exercise	In order to bear the claim carbohydrate-electrolyte solutions should contain 80 350 kcal/L from carbohydrates, and at least 75 % of the energy should be derived from carbohydrates which induce a high glycaemic response, such as glucose, glucose polymers and sucrose. In addition, these beverages should contain between 20 mmol/L (460 mg/L) and 50 mmol/L (1,150 mg/L) of sodium, and have an osmolality between 200 330 mOsm/kg water.	maintenance of endurance performance	No – considered under P1030	2011:9(6):22 11	Commission Regulation (EU) 432/2012 of 16/05/2012
Carbohydrate-electrolyte solutions	Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	In order to bear the claim carbohydrate-electrolyte solutions should contain 80 350 kcal/L from carbohydrates, and at least 75 % of the energy should be derived from carbohydrates which induce a high glycaemic response, such as glucose, glucose polymers and sucrose. In addition, these beverages should contain between 20 mmol/L (460 mg/L) and 50 mmol/L (1,150 mg/L) of sodium, and have an osmolality between 200 and 330 mOsm/kg water.	enhancement of water absorption during exercise	No – considered under P1030	2011:9(6):22 11	Commission Regulation (EU) 432/2012 of 16/05/2012

Nutrient, substance, food or food category	Claim	Conditions of use of the claim/Restrictions of use/Reasons for non-authorisation	Health relationship	Previously considered by FSANZ under P293	EFSA option reference/journal reference	Commission Regulation
Carbohydrates	Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle	The claim may be used only for food which provides carbohydrates which are metabolised by humans (excluding polyols). Information shall be given to the consumer that the beneficial effect is obtained with the consumption of carbohydrates, from all sources, at a total intake of 4 g per kg body weight, at doses, within the first 4 hours and no later than 6 hours, following highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle. The claim may be used only for foods intended for adults who have performed highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle.	-	No	Q-2013-00234	Commission Regulation (EU) 2015/7 of 06/01/2015
Creatine	Creatine increases physical performance in successive bursts of short-term, high intensity exercise	The claim may be used only for food which provides a daily intake of 3 g of creatine. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of creatine. The claim may be used only for foods targeting adults performing high intensity exercise.	increase in physical performance during short-term, high intensity, repeated exercise bouts	Yes – not included due to prohibition in Standard 2.9.4 on claims about performance on a sports food	2011:9(7):23 03	Commission Regulation (EU) 432/2012 of 16/05/2012
Creatine	Daily creatine consumption can enhance the effect of resistance training on muscle strength in adults over the age of 55.	Information shall be provided to the consumer that: the claim is targeting adults over the age of 55, who are engaged in regular resistance training, the beneficial effect is obtained with a daily intake of 3 g of creatine in conjunction with resistance training, which allows an increase in the workload over time and which should be performed at least three times per week for several weeks, at an intensity of at least 65 % - 75 % of one repetition maximum load* The claim may be used only for foods targeting adults over the age of 55, who are engaged in regular resistance training. *Repetition maximum load is the maximum weight or force an individual can exert in a single lift.	increase in physical performance during short-term, high intensity, repeated exercise bouts	No	Q-2015-00437	Commission Regulation (EU) 2017/672 of 07/04/2017
Protein	Protein contributes to the maintenance of muscle mass	The claim may be used only for food which is at least a source of protein as referred to in the claim SOURCE OF PROTEIN as listed in the Annex to Regulation (EC) No 1924/2006.	growth or maintenance of muscle mass	Yes – included in Schedule 4 (Part 3)	2010:8(10):1 811, 2011:9(6):22 03	Commission Regulation (EU) 432/2012 of 16/05/2012

Nutrient, substance, food or food category	Claim	Conditions of use of the claim/Restrictions of use/Reasons for non-authorisation	Health relationship	Previously considered by FSANZ under P293	EFSA option reference/journal reference	Commission Regulation
Protein	Protein contributes to a growth in muscle mass	The claim may be used only for food which is at least a source of protein as referred to in the claim SOURCE OF PROTEIN as listed in the Annex to Regulation (EC) No 1924/2006.	growth or maintenance of muscle mass	Yes – included in Schedule 4 (Part 3)	2010:8(10):1811 , 2011:9(6):2203	Commission Regulation (EU) 432/2012 of 16/05/2012
Vitamin C	Vitamin C contributes to maintain the normal function of the immune system during and after intense physical exercise	The claim may be used only for food which provides a daily intake of 200 mg vitamin C. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 200 mg in addition to the recommended daily intake of vitamin C.	function of the immune system during and after extreme physical exercise	Yes -claim in Schedule 4 refers only to maintenance of immune function (no reference to during/after physical activity)	2009:7(9):1226	Commission Regulation (EU) 432/2012 of 16/05/2012

1. Health claims which contribute to 'normal' physiological function have not been included e.g. contributes to normal muscle function (calcium, magnesium, potassium, vitamin D), contributes to normal mental performance (pantothenic acid). Nutrition claims have not been included.

Attachment C: Summary of submissions to P1010 Consultation Paper One relevant to nutrition content and health claims for sports foods

Theme	Detail	Raised by
Issues with existing framework for nutrition content claims and health claims for sports foods		
Restrictive for innovation	<ul style="list-style-type: none"> Lacks flexibility, limits innovation, and product development. The restrictive nature of the current framework disincentivises manufacturers from innovating within this space and does not support broader consumer informed choice. Limits the innovation in formulated supplementary sports foods, which could improve and expand the range of products for people who partake in exercise. 	Australia Food & Grocery Council Healthcare Product Specialists Australian Beverages Council Limited Nestle
Limit the ability to inform consumers of the benefits of sports foods. Do not enable consumers to make informed choices	<ul style="list-style-type: none"> Limited claim permissions do not enable benefits to be communicated to consumers. Does not allow for clear differentiation between products. 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. The current regulatory framework in Standard 2.9.4 is overly restrictive on provisions for making nutrient content or health claims beyond claiming the presence of a vitamin, mineral or nutritive substance in a sports food. The restriction on claims limits the information available to the consumer as to why the presence of that vitamin, mineral or nutritive substance is included in the sports food or drink. 	Australia Food & Grocery Council Healthcare Product Specialists Nestle New Zealand Food Safety New Zealand Food & Grocery Council Australian Beverages Council Limited
Issues/inconsistencies prohibition imposed by section 2.9.4—7 of the Code	<ul style="list-style-type: none"> The prohibition is in opposition to the Policy Guideline on the intent of Part 2.9 – Special Purpose Foods, as it prohibits information that can be provided to assist consumer understanding of the specific nature of sports foods, which are by definition to assist sports people in achieving specific nutritional and performance goals. The prohibition on sports foods is inconsistent with other countries such as the USA, Canada, and the EU. There is no safety-based justification for prohibiting health claims in connection with functional foods. General purpose foods have permission to make general level health claims under Standard 1.2.7 (if NPSC-compliant) about muscle building and repair, and energy production and release, however, this is not permitted for sports foods under Standard 2.9.4. 	Nestle Multinational beverage company Vitaco Health NZ New Zealand Food & Grocery Council Australia Food & Grocery Council
Vitamin and mineral claims	<ul style="list-style-type: none"> Formulated supplementary sports foods contain permitted vitamins, minerals and nutritive substances that have beneficial effects, some that are appropriate for sports foods can be found in Standard 1.2.7. For example, magnesium has a specific health 	Nestle New Zealand Food & Grocery Council

Theme	Detail	Raised by
	<p>effect 'contributes to a reduction of tiredness and fatigue' which would be an appropriate post workout benefit to inform consumers on the label of a sports food containing magnesium.</p> <ul style="list-style-type: none"> • Labelling requirements are restrictive for manufacturers particularly in relation to claims. The Code currently permits sports foods to make only nutrition content claims in relation to vitamins and minerals and then only in certain circumstances (a normal serving contains at least 10% *RDI or *ESADDI for that vitamin or mineral and the amount claimed is no more than an amount specified in S29—16). There is also no permission to use any other descriptors (e.g. good source) even though the formulated supplementary food might well be of interest to the consumer in other areas e.g. low in gluten or low in lactose. 	
Clarification on health claims	<ul style="list-style-type: none"> • Clarity is required on the application of 'restricted representations' as defined in section 2.9.4—7 to health claims/therapeutic indications. • While Standard 1.2.7 and Schedule 4 permits health claims on 'foods', the interpretation and application of Standard 2.9.4—7 is confusing. 	Healthcare Product Specialists
Usefulness of the labelling statements in Division 3 for particular sports foods (high carbohydrate supplement, protein energy supplement, energy supplement)		
Outdated/not fit for purpose	<ul style="list-style-type: none"> • Composition and categories in Division 3 do not reflect current sports food market or current best practice. • There is little research supporting the use of protein energy supplements during exercise. • If the Division 3 labelling provisions are retained, consideration should be given to other relevant sports foods/nutrients that could be included, recognising the need to also future proof for category innovation. 	Australia Food & Grocery Council Australian Institute of Sport Healthcare Product Specialists New Zealand Food Safety Vitaco Health NZ New Zealand Food & Grocery Council
Do not provide a clear benefit or purpose of the sports food,	<ul style="list-style-type: none"> • Vague and generalised statements. • Do not communicate 'enhanced performance or other beneficial effects'. • Should be expanded to allow manufacturers to communicate the purpose of the product to allow consumers to select products that best serve their needs. • Question the extent to which the currently permitted claims under Division 3 for sports foods are informative for consumers i.e., 'the product is useful before, during or after sustained strenuous exercise'. Without context as to why the product is 'useful' i.e., its physiological or nutritional purpose, consumers are informed only of direction of use or general function. 	Australia Food & Grocery Council New Zealand Food & Grocery Council Australian Beverages Council Limited
Not utilised	<ul style="list-style-type: none"> • Labelling statements are often not present on supplements that fall into these categories currently, and therefore are also likely unenforced. 	Bulk Nutrients and Bioflex Nutrition

Theme	Detail	Raised by
	<ul style="list-style-type: none"> Not many products fit within the compositional criteria necessary to support the statements in Division 3 so the use of these are very limited and restrictive. Many products such as energy bars are sold as general foods with sports representation and are consequently exempt from the requirements. 	<p>New Zealand Food & Grocery Council New South Wales Food Authority</p>
Does not align with sports nutrition research	<ul style="list-style-type: none"> The Division 3 statements are outdated and should be reviewed to reflect the current environment and sports nutrition research. Best practice relating to sports food prescription has evolved significantly in recent years. The existing labelling statements do not reflect this. 	<p>Australian Institute of Sport Sports Dietitians Australia New Zealand Food & Grocery Council</p>
Suggest applying AIS sport supplement framework	<ul style="list-style-type: none"> Suggest applying the AIS classification system that ranks sports foods and supplement ingredients into groups according to scientific evidence. 'Optional' labelling statements on sports foods should reflect current best practice and the language of the AIS Supplement Framework. Products that contain ingredients in Group A should be able to claim that the sports food or supplement ingredient 'can support or enhance sports performance' in ways that align with AIS findings. 	<p>Sports Dietitians Australia Australian Institute of Sport Revvies</p>
No concern	<ul style="list-style-type: none"> No concerns are raised with the current nutritional claims within Standard 2.9.4. 	<p>Queensland Health</p>
How Standard 1.2.7 – Nutrition, health and related claims could apply to sports foods?		
Consider that Standard 1.2.7 should apply to sports foods	<ul style="list-style-type: none"> 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 evolution. Standard 2.9.4 should enable industry to make nutrient content claims and general level health claims (including those of beneficial physiological effect), either via a preapproved list or the self-substantiation pathway in accordance with Standard 1.2.7. Given that sports foods are developed to assist sports people, it would benefit consumers if sports foods were permitted to make pre-approved health claims from Schedule 4 as well as self-substantiated general level health claims. Recommend FSANZ consider a pathway for sports foods (including sports drinks) to apply Standard 1.2.7 to this category. 	<p>Healthcare Product Specialists Nestle New Zealand Food Safety Sports Dietitians Australia Vitaco Health NZ Australian Beverages Council Limited</p>
Nutrient profiling scoring criterion (NPSC)	<ul style="list-style-type: none"> Appropriate that sports as a special purpose food should not be required to meet NPSC. It will be necessary to ensure that sports are differentiated from other foods so that general foods cannot be inappropriately categorised as sports foods in order to avoid meeting the NPSC. Need to consider how to manage sports foods that do not meet the NPSC. 	<p>New Zealand Food Safety Multinational beverage company Australia Food & Grocery Council</p>
Pre-approved health claims for sports foods	<ul style="list-style-type: none"> Standard 1.2.7 does not appear to have been created with sports foods in mind, so is largely irrelevant, except for protein claims. 	<p>Bulk Nutrients and Bioflex Nutrition Australian Institute of Sport</p>

Theme	Detail	Raised by
	<ul style="list-style-type: none"> If adopting Standard 12.7 should consider integrating a section relating to sports performance claims. 	
Reduced clarity at the food-medicine interface	<ul style="list-style-type: none"> Any attempt to apply Standard 1.2.7 (and Schedule 4) to Standard 2.9.4 would expand the already overly broad range of the standard. It may also result in additional grey areas and reduce existing clarity the standard currently provides from a food-medicine interface perspective. NSW notes that claims about physiological effects, such as gaining muscle; increasing mental focus; increasing metabolism; increasing stamina; increasing testosterone levels; reducing oestrogen levels or otherwise modifying hormone levels; losing weight or fat; preparing for workout; recovering from workout, reside in the <i>Therapeutic Goods (Declared Goods) Order 2019</i>. Section 1.2.7—8 explicitly prohibits claims from being therapeutic. 	Therapeutic Goods Administration New South Wales Food Authority
Preferred approach is for claims on sports foods to be limited to a list of pre-approved evidence-based claims and not allowing self-substantiation	<ul style="list-style-type: none"> Based on the volume of claims on the market as well as the significant rate of category innovation, post-market management of claims in its current form is likely to be untenable for regulators. Limiting claims to a list of pre-approved claims is consistent with the European Commission's current model and would support international consistency. The claims already approved for use in Europe could be leveraged as a starting point for a pre-approved list under the Code. This narrow area for permissible claims provides an opportunity to consider an approach to voluntary claims on sports foods that is similar to that applied to electrolyte drinks through Proposal 1030. This is to permit a small range of pre-approved claims but not permit self-substantiation. 	Victorian Department of Health and the Victorian Department of Energy Environment and Climate Action New South Wales Food Authority
Sports foods should not be permitted to carry health claims	<ul style="list-style-type: none"> Concern is raised about allowing self-substantiation for regulating sports supplements similar to the current health claim requirements, particularly those containing potentially novel foods or substances or nutritive substances. Consideration should be given to clarifying if some of the commonly used marketing terms on sports supplements, such as fat burning, keto and thermogenic, are health claims and should be subject to health claim requirements in the Code. Consideration could be given to limiting and standardising these types of claims about the functions of a product to claims that are scientifically accepted, accurate and demonstrated by evidence. 	Queensland Health