

18 August 2014
[16–14]

Call for submissions – Proposal P1030

Health Claims – Formulated Supplementary Sports Foods & Electrolyte Drinks

FSANZ has assessed a proposal and has prepared a draft food regulatory measure to permit formulated supplementary sports foods (FSSFs), electrolyte drinks and electrolyte drink bases (EDs) to carry health claims related to their respective purposes. Given their related purpose, this proposal also transfers 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. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word ‘Submission’ and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 30 September 2014

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Executive summary

FSANZ has prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code) to permit formulated supplementary sports foods (FSSFs), electrolyte drinks and electrolyte drink bases (EDs) to carry health claims consistent with their intended purposes related to exercise or physical performance. Also, based on the similarity in purpose of the two foods, the draft variation transfers 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.

The Code recognises that FSSFs and EDs are each formulated to achieve a specific purpose. When these foods meet their respective prescribed composition, certain labelling claims relating to their purpose are permitted. For example, high carbohydrate FSSF can carry claims that the product is useful before, during or after sustained strenuous exercise. Before gazettal in January 2013 of Standard 1.2.7 – Nutrition Health and Related Claims, only one other health claim was permitted in the Code (folate and neural tube defects).

Standard 1.2.7 permits foods generally to carry health claims, including about physical performance, providing certain criteria are met. However, the Code prevents FSSFs and EDs from carrying health claims consistent with their specific purposes except for a very limited number of claims. This Proposal addresses this anomaly.

The draft variation permits both FSSFs and EDs to carry health claims relating to their respective purposes i.e. for FSSFs, to assist sports people in achieving specific nutritional or performance goals; and for EDs, for the rapid replacement of fluid, carbohydrates and electrolytes lost as a result of sustained strenuous physical activity. The health claims already permitted by the Code in relation to these foods will remain. Substantiation requirements and other conditions for making health claims in Standard 1.2.7 will apply. However the requirement to meet the nutrient profile scoring criterion (NPSC) does not apply, in keeping with the existing arrangements in Standard 1.2.7 i.e. foods standardised in Part 2.9 of the Code do not need to meet the NPSC when carrying a health claim.

The draft variation also proposes transferring the regulation of EDs from Standard 2.6.2 to Standard 2.9.4. This recognises the purpose of EDs as foods specifically formulated for strenuous physical activity, rather than as lifestyle products not specifically formulated for sports people. This approach is consistent with feedback from previous targeted stakeholder consultation and the findings of FSANZ consumer research.

The current definition of an ED is a *drink formulated and represented as suitable for the rapid replacement of fluid, carbohydrates, electrolytes and minerals*. The draft variation proposes to change the definition by removing the reference to minerals because there is no mandatory compositional requirement to include minerals, other than sodium, which can be considered a mineral or an electrolyte. Also, it proposes to remove the need for EDs to be 'represented as'. This is proposed to be replaced by a new requirement for a prescribed name – 'electrolyte drink' which will help enforcement agencies identify these products.

Changes are also proposed to the way compositional requirements for FSSFs and EDs are presented in the Code but the actual compositional permissions and requirements have not changed.

1 Introduction

1.1 The Proposal

The Proposal was prepared to:

- permit formulated supplementary sports foods (FSSFs), electrolyte drinks and electrolyte drink bases (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.

This Proposal aims to deliver an interim arrangement pending the future review of Standard 2.9.4.

1.2 Reasons for preparing the Proposal

FSSFs and EDs each have a prescribed composition to achieve an intended purpose which is related to exercise or physical performance. With the introduction of Standard 1.2.7, most foods can carry health claims, including claims about physical performance, providing certain claim criteria are met. However, apart from a few limited claims already permitted in Standard 2.9.4 and Standard 2.6.2, FSSFs and most EDs are not able to carry health claims consistent with their respective intended purpose. This Proposal addresses this anomaly.

1.3 The current Standards

Standard 1.2.7 regulates the conditions under which nutrition content and health claims on foods can be made, including requirements for self-substantiating food-health relationships that underpin general level health claims (GLHC) and the need for a food to meet the nutrient profiling scoring criterion (NPSC) to be eligible to carry a health claim.

Standard 1.2.7 does not apply to claims expressly permitted elsewhere in the Code. In addition, subclause 17(5) of Standard 1.2.7 states that *a food that is standardised in Part 2.9 of this Code does not need to meet the NPSC* when making a health claim. The transition period for Standard 1.2.7 ends in January 2016. During the transition period, a food must comply with Standard 1.2.7 or with the Transitional Standard 1.1A.2 – Health Claims, but not both.

Part 2.9 of the Code regulates special purpose foods which have a prescribed composition related to a particular intended purpose. Standard 2.9.4 regulates the composition and labelling of FSSFs which are foods or mixture of foods specially formulated to assist sports people in achieving nutritional or performance goals.

Division 1 – Formulated Supplementary Sports Foods Generally in Standard 2.9.4 regulates the composition and labelling of all FSSFs. In relation to labelling, FSSFs must carry advice that such foods are not suitable for pregnant women or children under 15 years of age; and that they must be used under medical or dietetic supervision. Division 2 – Particular Formulated Supplementary Sports Foods, permits particular FSSFs that meet one of three types of compositional specifications (high carbohydrate; protein energy, or energy) to carry certain claims on their labels e.g. *the product is useful before, during and after sustained strenuous exercise*. Apart from these claims permitted under Division 2, clause 6 of Standard 2.9.4 prohibits representations about enhanced athletic performance and beneficial physiological effects, by the following:

Unless specific permission is given in this Part, 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.

Standard 2.6.2 regulates packaged water and water-based beverages. It defines an electrolyte drink as *a drink formulated and represented as suitable for the rapid replacement of fluid, carbohydrates, electrolytes and minerals* and electrolyte drink bases as *a solid or liquid which when made up, makes an electrolyte drink*. Compositional requirements are also prescribed for EDs as shown in Table 1.

Table 1: Prescribed composition of electrolyte drinks and electrolyte drink bases

Carbohydrate (specified sugars)	50-100 g/L
Sodium	>10 mmol/L
Osmolality (isotonic only)	250-340 milliOsmol/L

Standard 2.6.2 permits isotonic electrolyte drinks to carry a claim to the effect that *the product is designed to promote the availability of energy and to prevent or treat mild dehydration that may occur as a result of sustained strenuous exercise.*

1.4 Procedure for assessment

The Proposal is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Health Claims

The Code recognises that FSSFs and EDs are foods each formulated to achieve a specific purpose: FSSFs to help sports people achieve nutritional or performance goals; and EDs to help with rapid replacement of fluid, carbohydrates and electrolytes. Where these foods meet a prescribed composition, a limited number of claims relating to the purpose of the food are permitted. These claims comprised most of the permitted health claims in the Code before the introduction of Standard 1.2.7, with the other health claim relating to folate and neural tube defects.

The introduction of Standard 1.2.7 in the Code provides for health claims to be made about foods, including health claims about physical performance, providing such foods meet certain claim criteria. However, FSSFs and most EDs are prevented from making health claims except where express permission is provided in Standards 2.9.4 and 2.6.2 for making certain claims.

EDs are considered to be one type of product on the market in the sports drink category. Unlike other products in this category, the Code prescribes the minimum and maximum quantity of sugars and a minimum sodium level in order for EDs to achieve the specific purpose of rapid replacement of fluid, electrolytes and carbohydrates. No such minimum sugar composition requirement exists for sports drinks not regulated as EDs. The prescribed sugars content for EDs in general disqualifies them from meeting the NPSC and therefore from carrying health claims (apart from their one permitted claim).

The draft variation proposes that FSSFs and EDs be permitted to carry health claims relating to their respective intended purpose in accordance with the requirements in Standard 1.2.7, which allows for self-substantiated claims. The existing claims permitted in the Code for these foods will be retained.

Consistent with the current provisions for special purpose foods, FSSFs and EDs carrying such claims will not have to meet the NPSC. The reason for this is that these foods are specially formulated for specific dietary purposes and must meet certain prescribed compositional requirements related to those purposes. Limiting permitted health claims to the purpose of the food will reduce the potential for consumers to be misled as to the overall health value and purpose of the foods.

Standard 1.2.7 regulates nutrition content claims as well as health claims. The draft variation makes a minor amendment to Schedule 1 of Standard 1.2.7 to provide the conditions that must be met when making pre-approved health claims about specific vitamins or minerals in relation to FSSFs. However, the draft variation does not change existing requirements for making nutrition content claims about FSSFs and EDs.

Apart from permitting FSSF to carry health claims related to their intended purpose, the draft variation proposes no other changes to the regulation of FSSF.

2.2 Electrolyte Drinks

2.2.1 Definition

The current definition of an ED is a *drink formulated and represented as suitable for the rapid replacement of fluid, carbohydrates, electrolytes and minerals*. FSANZ is proposing to change the definition by removing the reference to minerals, because there is no mandatory compositional requirement to include minerals, other than sodium, which can be considered as a mineral or an electrolyte.

Also, as the Proposal will broaden the permitted health claims for EDs, the requirement in the definition for EDs to be 'represented as' has become superfluous. The proposed new definition also strengthens the association of consumption of EDs with their intended purpose and use for sustained strenuous physical activity.

The proposed new definition is: **electrolyte drink** means a *drink formulated for the rapid replacement of fluid, carbohydrates and electrolytes lost as a result of sustained strenuous physical activity*.

2.2.2 Electrolyte Drinks as a Special Purpose Food

The draft variation transfers regulation of EDs to a new division of Standard 2.9.4 to more clearly recognise the purpose of EDs as a food specifically formulated for strenuous physical activity, rather than as a lifestyle product not specifically formulated for sports people. This transfer is consistent with targeted consultation with industry and jurisdictions in 2011 and the findings of FSANZ consumer research¹ which showed consumers consider EDs to be a sports food.

Foods regulated by Part 2.9 (including Standard 2.9.4) are considered special purpose foods that are formulated for specific dietary purposes.

¹ <http://www.foodstandards.gov.au/publications/Pages/Sports-Foods-Consumption-in-Australia-and-New-Zealand.aspx>

Special purpose foods have prescribed compositional requirements and can have specific labelling requirements to address any potential risks associated with the composition of the food. The Australia and New Zealand Ministerial Forum on Food Regulation² has issued a Policy Guideline³ on the Intent of Part 2.9 – Special Purpose Foods. FSANZ is required to have regard to this guideline and considers the transfer of EDs and the draft variation to be consistent with the guideline, see analysis at Appendix 1. Transferring regulation of EDs from Standard 2.6.2 to Standard 2.9.4 does not change the composition requirements for EDs nor does it change the existing labelling requirements. However, FSANZ is proposing including a prescribed name and updated nutrition information requirements as discussed below.

The food additive permissions for water-based flavoured drinks that apply to EDs and the permissions listed under electrolyte drinks and electrolyte drink bases currently found in Schedule 1 of Standard 1.3.1 – Food Additives will be moved to the Special Purpose Foods section of that Schedule.

2.2.3 Prescribed Name

Standard 1.2.2 – Food Identification Requirements, requires that the label on a package of food must include the prescribed name of the food (if a name is prescribed by the Code) and in any other case, a name or description of the food sufficient to indicate the true nature of the food. ‘Formulated supplementary sports food’ is a prescribed name in the Code. With the transfer of regulation of EDs to Standard 2.9.4 and the removal of the requirement in the definition for EDs to be ‘represented as’, a prescribed name of ‘electrolyte drink’ has been set in place of manufacturers’ descriptions of the true nature of the food, to help enforcement agencies clearly identify EDs. This is consistent with the approach taken for other foods regulated by Part 2.9 of the Code.

2.2.4 Nutrition information requirements for EDs

A nutrition information panel is currently required on the label of EDs, by Standard 1.2.8 – Nutrition Information Requirements. Additionally, EDs are currently required by Standard 2.6.2 to include a declaration on the label of the average energy value; total carbohydrate, including each type of monosaccharide and disaccharide present; and the milligrams and millimoles of added minerals and electrolytes, per 100 mL of the ED as ready to drink.

The draft variation transfers the additional nutrition information requirements for EDs from Standard 2.6.2 to Standard 2.9.4 and aligns them with the provisions in Standard 1.2.8 for nutrition information panels. This provides consistency in the requirements for the presentation of nutrition information on ED labels to support consumer use. As requirements to declare the ‘average quantity’ of carbohydrate and the ‘average energy content’ are already set out in Standard 1.2.8, the requirements to declare ‘total carbohydrate’ and ‘average energy value’ have not been included in Standard 2.9.4.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ’s standards development process.

The communication strategy for this Proposal aims to ensure that stakeholders are aware of any changes to the Code which may result from this work. This proposed draft variation to the Code is provided on the FSANZ website for public consultation.

² convening as the Australia and New Zealand Food Regulation Ministerial Council

³ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

Following this consultation period, FSANZ will review the nature of the feedback received from submitters and determine whether additional communication or consultation is required before final consideration by the FSANZ Board. Every submission on an application or proposal is considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and the Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards so amending the Code as described above is unlikely to have a significant effect on international trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

2.4.1 Section 59

2.4.1.1 Cost benefit analysis

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Proposal outweigh the costs to the community, government and industry that would arise from the development or variation of the food regulatory measure.

The Office of Best Practice Regulation (OBPR) has advised FSANZ that the Proposal is likely to have a minor regulatory impact on business and individuals and that a COAG Regulatory Impact Statement (RIS) is not required to be prepared (OBPR ID: 16662). Affected parties may include the following:

Industry: FSANZ considers that the draft variation will provide manufacturers of FSSFs and EDs with the opportunity to carry a broader range of health claims consistent with the respective intended purpose of the foods. Although a limited range of claims is already permitted, FSSFs and EDs will be able to carry other health claims as can be made for other foods, providing that such health claims are pre-approved or can be scientifically substantiated. Electrolyte drink manufacturers are already required to include a name or description of the electrolyte drink sufficient to indicate the true nature of the food – the words 'electrolyte drink' are often used. Therefore the requirement to change to a prescribed name on EDs is small, relative to the likely benefits of the permission to carry health claims without meeting the pre-existing eligibility requirement of the NPSC.

Consumers: Health claims that relate to the purpose of the product will be supported by scientific evidence to the same degree of certainty, whether they be pre-approved by FSANZ or self-substantiated. This consistency will benefit consumers as products may be able to carry a broader range of substantiated claims.

Government: There are no additional costs to government as the draft variation uses the existing health claims framework and substantiation requirements in the Code. A prescribed name has been established to assist enforcement agencies to identify the products that are not required to meet the NPSC.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure varied as a result of the Proposal.

2.4.1.3 Any relevant New Zealand standards

The draft variations amend joint Australia New Zealand standards. There are no relevant New Zealand only standards.

2.4.1.4 Any other relevant matters

There are no other relevant matters.

2.4.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

Apart from presentational changes, no changes are proposed to the composition permissions or requirements for FSSFs and EDs in this Proposal. Therefore public health and safety will continue to be protected.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The draft variation permits health claims consistent with the purpose of FSSFs and EDs as outlined in their respective definitions. Health claims can provide sports people with information to help make food choices appropriate for their nutritional or performance goals.

2.4.2.3 The prevention of misleading or deceptive conduct

The draft variation relies on the protection afforded by the requirements in Standard 1.2.7 to mitigate the possibility of consumers being misled by health claims. These requirements include qualifying criteria for foods carrying health claims, the need for all health claims to be substantiated and requirements for dietary context statements to be made in association with health claims. Furthermore, health claims about FSSFs and EDs are limited to those consistent with the respective purposes of FSSFs and EDs as defined.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

Since the Proposal does not propose any change to composition or pre-approval of health claims, no scientific risk assessment has been undertaken by FSANZ.

- **the promotion of consistency between domestic and international food standards**

The draft variation will allow internationally traded FSSFs and EDs that meet composition requirements of the Code to carry scientifically substantiated health claims. The regulatory requirements for health claims are not inconsistent with those in the European Union, USA and Canada.

- **the desirability of an efficient and internationally competitive food industry**

The draft variation removes a potential barrier to internationally traded FSSFs and EDs by permitting a broader range of scientifically substantiated claims that relate to their respective intended purposes.

- **the promotion of fair trading in food**

The draft variation promotes fair trading by permitting FSSFs and EDs to carry a broader range of scientifically substantiated health claims that are consistent with their respective purposes and in accordance with Standard 1.2.7.

- **any written policy guidelines formulated by the Ministerial Council⁴,**

Two Ministerial policy guidelines⁵ are relevant for this regulatory measure:

- Intent of Part 2.9 – Special Purpose Foods
- Nutrition, Health and Related Claims.

An analysis of the draft variation against the Policy Guideline on the Intent of Part 2.9 – Special Purpose Foods is at Appendix 1.

FSSFs and EDs have been demonstrated as safe for use by the intended population. As there is no demonstrated risk to public health and safety, there is no requirement to increase controls to restrict access to these products.

The new provisions allow certain health claims to be made about FSSFs and EDs, in accordance with Standard 1.2.7. FSANZ had regard to the *Policy Guideline on Nutrition, Health and Related Claims* when developing Standard 1.2.7.

3 Draft variation

3.1 Draft variation and explanatory statement

The draft variation is at Attachment A.

⁴ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

⁵ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

The draft variation contains the changes to Standards 1.2.7, 2.6.2 and 2.9.4 that have been discussed in this Assessment Report. It also contains consequential amendments to Standard 1.3.1 which regulates the use of food additives in the production and processing of food.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

3.2. Transitional arrangements

The draft variation is intended to take effect on gazettal, with a transition period until 18 January 2016, which aligns with the transition period of Standard 1.2.7.

FSANZ is reviewing the Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025 – Code Revision – details of which are on the FSANZ website⁶. FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has changed the Code's structure and format. A further draft revision of the Code and call for submissions was released in July 2014.

The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it is expected that the new Code will commence in 2015 and will repeal and replace the current Code.

Due to the timing of P1025, the new Code may not capture the amendments in the draft variation proposed by P1030 at Attachment A. Therefore, once commenced, the new Code will have to be amended to incorporate any outstanding changes made to the current Code, including the variation at Attachment A.

3.3. Implementation and review

The draft variation is intended to be an interim arrangement pending the FSANZ review of Standard 2.9.4. The variations are expected to be gazetted before the commencement of the review of that Standard.

Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

⁶ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

Special Purpose Foods: Analysis of draft variation against policy guideline

Electrolyte Drinks	
Definition	<i>A drink formulated for the rapid replacement of fluid, carbohydrates and electrolytes lost as a result of sustained strenuous physical activity</i>
Scope and Aim of Part 2.9 Policy Guideline	
Part 2.9 - Special Purpose Foods, of the Code is intended to contain food standards that prescribe specific requirements for foods processed or manufactured for use by physiologically vulnerable individuals and population sub-groups.	EDs are foods processed or manufactured for use by persons requiring rapid replacement of fluid, carbohydrate and electrolytes (such as when depleted as a result of sustained exercise). They are a subset of food intended to assist with physiological demands placed on sports people. As such they constitute foods processed or manufactured for use by physiologically vulnerable individuals and population sub-groups, namely those requiring altered energy intake.
Requirements within food standards in Part 2.9 are prescribed relative to the particular intended dietary use of the food.	The intended dietary use of EDs is to replenish fluid, carbohydrates and electrolytes. The Code therefore prescribes the minimum and maximum amount of carbohydrate and minimum sodium content to achieve the intended dietary use. The proposed health claims are related to the intended dietary use.
For the purpose of Part 2.9, physiological vulnerability relates only to 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	No specific life stage identified. No physical disease, disorder or disability
physical and physiological conditions that require altered energy intake;	Physical activity can require increased energy intake or increased intake in the form of fluid, carbohydrate, electrolytes, and minerals.
Specific Policy Principles	
Special purpose foods should be targeted only to those population groups satisfying the definition presented in the Scope/Aim section.	Sports people are an identified target group, and are physiologically vulnerable after strenuous exercise.
The composition of special purpose food should be consistent with the intended purpose.	The Code mandates the minimum and maximum carbohydrate content and the minimum sodium content of EDs. Products that are outside this compositional range are more suited for lifestyle users than sports people and are not regulated by this standard.
Adequate information should be provided, including through labelling and advertising of special purpose foods, to:	
<ul style="list-style-type: none"> assist consumer understanding of the specific nature of the food, the intended population group and intended special purpose of the food; and 	Specific labelling requirements for ED include declaration of nutrition information including each type of monosaccharide and disaccharide present and quantity of added minerals and electrolytes. It is proposed that ED will be permitted to make health claims relating to their intended purpose, i.e. to achieve rapid replacement of fluid, carbohydrates, and electrolytes lost as a result of sustained strenuous activity.

	Electrolyte Drinks
<ul style="list-style-type: none"> provide for safe use by the intended population and to help prevent inappropriate use by those for whom the special purpose food is not intended. 	<p>The recommended volume and frequency of use are labelling requirements.</p>
<p>Consideration, where appropriate, should be given to application of controls to restrict access to a special purpose food on the basis of risk to public health and safety.</p>	<p>There is no evidence of risks to consumers that would warrant limiting access of these products.</p>

Attachment A – Draft variations to the *Australia New Zealand Food Standards Code*



Food Standards (Proposal P1030 – Health Claims – Formulated Supplementary Sports Foods & Electrolyte Drinks) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1030 – Health Claims – Formulated Supplementary Sports Foods & Electrolyte Drinks) Variation*.

2 Variation to Standards in the Australia New Zealand Food Standards Code

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

SCHEDULE

[1] Standard 1.2.7 is varied by inserting in Columns 2, 3 and 4 of Schedule 1 after the last entry for “Vitamin or mineral (not including potassium or sodium)”

“

If the food is a formulated supplementary sports food standardised under Standard 2.9.4, the food meets the conditions for making a claim about vitamins and minerals in subclause 5(2) of Standard 2.9.4		
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”

[2] Standard 1.3.1 is varied by

[2.1] omitting from item 14.1.3 in Schedule 1

“

electrolyte drink and electrolyte drink base

-	Aspartame	150	mg/kg
950	Acesulphame potassium	150	mg/kg
962	Aspartame-acesulphame salt	230	mg/kg

”

[2.2] inserting after item 13.4.2 in Schedule 1

“

13.5 Electrolyte drink and electrolyte drink base*

-	Quinine	100	mg/kg	tonic drinks, bitter drinks and quinine drinks only
123	Amaranth	30	mg/kg	
200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	400	mg/kg	
210 211 212 213	Benzoic acid and sodium, potassium and calcium benzoates	400	mg/kg	
220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	115	mg/kg	
243	Ethyl lauroyl arginate	50	mg/kg	

385	Calcium disodium EDTA	33	mg/kg	products containing fruit flavouring, juice or pulp or orange peel extract only
444	Sucrose acetate isobutyrate	200	mg/kg	
445	Glycerol esters of wood rosins	100	mg/kg	
480	Dioctyl sodium sulphosuccinate	10	mg/kg	
950	Acesulphame potassium	150	mg/kg	
951	Aspartame	150	mg/kg	
954	Saccharin	150	mg/kg	
956	Alitame	40	mg/kg	
960	Steviol glycosides	200	mg/kg	
962	Aspartame-acesulphame salt	230	mg/kg	
999(i) and (ii)	Quillaia saponins (from Quillaia extract type 1 and type 2)	40	mg/kg	

[2.3] omitting the heading “13.5 Food for special medical purposes*” in Schedule 1 and substituting “13.6 Food for special medical purposes*”

[2.4] omitting the heading “13.5.1 Liquid food for special medical purposes*” in Schedule 1 and substituting “13.6.1 Liquid food for special medical purposes*”

[2.5] omitting the heading “13.5.2 Food for special medical purposes other than liquids*” in Schedule 1 and substituting “13.6.2 Food for special medical purposes other than liquids*”

[3] **Standard 2.6.2** is varied by

[3.1] omitting the Purpose and substituting

“Purpose

This Standard deals with packaged waters and water-based beverages which contain food additives and in certain cases, nutritive substances. The Standard defines a number of products and sets certain compositional requirements for packaged water, brewed soft drinks and formulated beverages. The Standard also permits the voluntary addition of fluoride to water presented in packaged form.

Labelling requirements specific to water presented in packaged form are included in this Standard. This Standard also prohibits the labelling or presentation of non-alcoholic beverages in such a way as to suggest the product is an alcoholic beverage.”

[3.2] omitting the definitions of **electrolyte drink** and **electrolyte drink base** in clause 1

[3.3] omitting the definition of **non-alcoholic beverage** in clause 1 and substituting

“non-alcoholic beverage means –

- (a) packaged water; or
- (b) a water-based beverage which may or may not contain other foods, except for alcoholic beverages.”

[3.4] omitting clauses 6 to 8

[3.5] omitting the heading to clause 9 and substituting “6 Composition of formulated beverages”

[3.6] updating the Table of Provisions to reflect these variations

[4] **Standard 2.9.4** is varied by

[4.1] omitting the heading of the Standard and substituting “Formulated Supplementary Sports Foods and Electrolyte Drinks”

[4.2] omitting the Purpose and substituting

“Purpose

This Standard defines and regulates the composition and labelling of foods specially formulated to assist sports people in achieving specific nutritional or performance goals, and electrolyte drinks. Such foods are intended as supplements to a diet rather than for use as the sole or principal source of nutrition.

Due to the particular physiological demands of sports people, this Standard provides for the addition to formulated supplementary sports foods of certain micronutrients and other ingredients which are not permitted to be added to other foods. This means that such products are not suitable for consumption by children.”

[4.3] omitting the heading of Division 1 and substituting “Division 1 – Introduction”

[4.4] omitting clause 1 and substituting

“1 Interpretation

(1) In this Code –

electrolyte drink means a drink formulated for the rapid replacement of fluid, carbohydrates and electrolytes lost as a result of sustained strenuous physical activity.

electrolyte drink base means a solid or liquid which when made up, makes an electrolyte drink.

formulated supplementary sports food means a food or mixture of foods specifically formulated to assist sports people in achieving specific nutritional or performance goals, and does not include electrolyte drinks and electrolyte drink bases.

one-day quantity in relation to formulated supplementary sports food, means the amount of that food which is to be consumed in one day in accordance with directions specified in the label.

(2) In Division 4 of this Standard –

the Variation means the *Food Standards (Proposal P1030 – Health Claims – Formulated Supplementary Sports Foods & Electrolyte Drinks) Variation.*”

[4.5] inserting after clause 1

“Division 2 – Formulated Supplementary Sports Foods Generally”

[4.6] omitting clause 6 and substituting

“6 Health claims

(1) This clause does not apply to a statement that is permitted by Division 3.

(2) A health claim made about a formulated supplementary sports food must –

(a) be made in accordance with Standard 1.2.7; and

(b) relate only to the specific nutritional or performance goal or goals for sports people that the food was formulated to achieve.”

[4.7] omitting the heading of Division 2 and substituting “Division 3 – Particular Formulated Supplementary Sports Foods”

[4.8] inserting after clause 9

“Division 4 – Electrolyte Drinks and Electrolyte Drink Bases

10 Application of Divisions 2 and 3 to electrolyte drinks and electrolyte drink bases

Divisions 2 and 3 do not apply to electrolyte drinks and electrolyte drink bases.

11 Application of stock-in-trade provision

Subclause 1(2) of Standard 1.1.1 does not apply to the amendments made by the Variation in relation to electrolyte drinks and electrolyte drink bases.

12 Transitional arrangement to 18 January 2016

(1) Notwithstanding clauses 14 to 17, during the transitional period, an electrolyte drink or electrolyte drink base may comply with either –

- (a) the Code; or
- (b) the Code as if the Variation had not commenced,

but not a combination of both.

(2) For the purposes of this clause, **transitional period** means the period of time that commences on the commencement date of the Variation and ends on 18 January 2016.

13 Stock-in-trade period (19 January 2016 –18 January 2017)

(1) Notwithstanding clauses 14 to 17, during the stock-in-trade period, an electrolyte drink or electrolyte drink base may comply with either –

- (a) the Code; or
- (b) the Code as if the Variation had not commenced, provided that the food product complied with that version of the Code during the transitional period,

but not a combination of both.

(2) For the purposes of this clause, **the stock-in-trade period** means the period of time that commences on 19 January 2016 and ends on 18 January 2017.

14 Composition of electrolyte drinks and electrolyte drink bases

(1) An electrolyte drink, or an electrolyte drink base when made up according to directions, must contain no less than 10 mmol/L of sodium.

(2) An electrolyte drink, or an electrolyte drink base when made up according to directions, must contain –

- (a) no less than 50 g/L and no more than 100 g/L total –
 - (i) dextrose; and
 - (ii) fructose; and
 - (iii) glucose syrup; and
 - (iv) maltodextrin; and
 - (v) sucrose; and

- (b) no more than 50 g/L fructose.

(3) An electrolyte drink, or an electrolyte drink base when made up according to directions, may contain –

- (a) calcium phosphates; and
- (b) potassium phosphates; and
- (c) calcium citrates; and
- (d) potassium citrates; and
- (e) sodium citrates; and
- (f) potassium carbonates, including potassium bicarbonate; and
- (g) potassium chloride; and
- (h) calcium chloride; and
- (i) sodium chloride; and
- (j) calcium lactate; and
- (k) magnesium lactate; and
- (l) magnesium sulphate.

15 Labelling of electrolyte drinks and electrolyte drink bases

(1) The label on a package of electrolyte drink or electrolyte drink base must include a nutrition information panel.

(2) The nutrition information panel referred to in subclause (1) must include a declaration of the average quantity per serving and per unit quantity, as ready to drink, of –

- (a) each type of monosaccharide and disaccharide present; and
- (b) milligrams and millimoles of the added minerals and electrolytes.

(3) The information prescribed in subclause (2) must be provided in accordance with clause 4 of Standard 1.2.8 if –

- (a) a claim requiring nutrition information is made about an electrolyte drink or electrolyte drink base; and
- (b) the electrolyte drink or electrolyte drink base is not required to bear a label pursuant to clause 2 of Standard 1.2.1.

(4) Electrolyte drink is a prescribed name for electrolyte drinks and electrolyte drink bases.

(5) For the purposes of this clause, **unit quantity** has the meaning given by Standard 1.2.8.

(6) For the purposes of this clause, **a claim requiring nutrition information** has the meaning given by Standard 1.2.8.

16 Health claims about electrolyte drinks and electrolyte drink bases

A health claim made about an electrolyte drink or an electrolyte drink base must –

- (a) be made in accordance with Standard 1.2.7; and
- (b) relate only to the rapid replacement of fluid, carbohydrates and electrolytes lost as a result of sustained strenuous physical activity.

17 Claims in relation to the tonicity of electrolyte drinks

(1) A claim that an electrolyte drink is isotonic may only be made if the electrolyte drink has an average osmolality of 250–340 milliOsmol/L.

(2) Where a claim is made that an electrolyte drink is isotonic, hypertonic or hypotonic, the osmolality of the electrolyte drink as measured in milliOsmol/L must be declared on the label of the package.

(3) The label on a package of isotonic electrolyte drink may include words to the effect that the product is designed to promote the availability of energy and to prevent or treat mild dehydration that may occur as a result of sustained strenuous exercise.”

[4.9] updating the Table of Provisions to reflect these variations

Attachment B – Draft Explanatory Statement

Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1030 to permit formulated supplementary sports foods and electrolyte drinks, electrolyte drink bases to carry health claims on their labels and in advertising and to transfer the regulation of electrolyte drinks and electrolyte drink bases from Part 2.6 to Part 2.9 of the Code. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft variation.

2. Purpose

The Authority has approved a draft variation that permits formulated supplementary sports foods and electrolyte drinks, electrolyte drink bases to carry health claims related to their purpose. These claims must be made in accordance with the requirements of Standard 1.2.7 – Nutrition, Health and Related Claims. The draft variation does not change the compositional permissions for formulated supplementary sports foods, electrolyte drinks and electrolyte drink bases; or the permissions for nutrition content claims.

In addition, the draft variation transfers the regulation of electrolyte drinks and electrolyte drink bases from Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drinks to Standard 2.9.4 – Formulated Supplementary Sports Foods. This recognises that electrolyte drinks and electrolyte drink bases are formulated for a specific purpose, have prescribed composition to achieve that purpose, and as such, are better regulated in the section of the Code that relates to special purpose foods.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1030 will include one round of public consultation following an assessment and the preparation of a draft variation and associated report.

A Regulation Impact Statement was not required because the proposed variations to Standards 1.2.7, 1.3.1, 2.6.2 and 2.9.4 are likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Standard 1.2.7 – Nutrition, Health and Related claims

Item [1] amends Schedule 1 – Conditions for Nutrition Content Claims of Standard 1.2.7. It inserts a new condition in the entry in the Schedule for ‘Vitamin or mineral (not including potassium or sodium)’. The amendment requires that the conditions listed in subclause 5(2) of Standard 2.9.4 for making a claim about the presence of a vitamin or mineral in a formulated supplementary sports food must be met when making a nutrition content claim listed in Schedule 1 or health claims listed in either Schedule 2 or 3 of Standard 1.2.7, under the Standard, in relation to a vitamin or mineral in a formulated supplementary sports food.

Standard 1.3.1 – Food Additives

Item [2] amends Schedule 1 in Standard 1.3.1. It transfers the food additive permissions specific to electrolyte drinks and electrolyte drink bases from subitem 14.1.3 in Schedule 1 of Standard 1.3.1 to a new subitem under item 13 of that Schedule. The new subitem is headed ‘13.5 Electrolyte drink and electrolyte drink base*’.

The food additive permissions listed under the new subitem also include the permissions listed under subitem 14.1.3 which have applied generally to electrolyte drinks and electrolyte drink bases as water-based flavoured drinks. The more restrictive maximum permitted levels set by the food additive permissions specific to electrolyte drinks and electrolyte drink bases in subitem 14.1.3 have been retained in the new subitem. The general permissions listed in subitem 14.1.3 for water-based flavoured drinks remain unchanged.

Current subitems 13.5, 13.5.1 and 13.5.2 in Schedule 1 have been renumbered.

Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drinks

Item [3] amends Standard 2.6.2 to remove references to electrolyte drinks and electrolyte drink bases, as well as the requirements specifically relating to electrolyte drinks and electrolyte drink bases. The amendments are as follows.

Subitem [3.1] substitutes the Purpose statement for Standard 2.6.2 to reflect that electrolyte drinks and electrolyte drink bases are no longer covered by that Standard.

Subitem [3.2] omits the definitions of ‘electrolyte drink’ and ‘electrolyte drink base’ in clause 1.

Subitem [3.3] substitutes the definition of ‘non-alcoholic beverage’ in clause 1 to remove the reference in that definition to electrolyte drinks.

Subitem [3.4] omits clauses 6 to 8. They are provisions that specifically relate to electrolyte drinks and electrolyte drink bases.

Subitem [3.5] renumbers clause 9 to reflect the new structure of Standard 2.6.2.

Subitem [3.6] updates the Table of Provisions in Standard 2.6.2 to reflect the amendments made to that Standard.

Standard 2.9.4 – Formulated Supplementary Sports Foods

Item 4 amends Standard 2.9.4 as follows.

Subitem [4.1] substitutes the heading of Standard 2.9.4 to include electrolyte drinks.

Subitem [4.2] substitutes the Purpose statement of Standard 2.9.4 to reflect that the Standard now relates to electrolyte drinks and electrolyte drink bases, as well as formulated supplementary sports foods.

Subitems [4.3] and [4.7] amend existing headings in Standard 2.9.4 as a consequence of re-structuring the Standard.

Subitem [4.4] substitutes clause 1 with two new subclauses. This is to include new and amended definitions and to differentiate between definitions that apply to the Code and the new definition of 'the Variation', which applies only to Division 4 of Standard 2.9.4.

Definitions of 'electrolyte drink' and 'electrolyte drink base', previously located in Standard 2.6.2, are inserted in clause 1. The definition of 'electrolyte drink' has been changed to mean a drink formulated for the rapid replacement of fluid, carbohydrates and electrolytes lost as a result of sustained strenuous physical activity.

The pre-existing definition of 'formulated supplementary sports food' in clause 1, has been changed to mean food or a mixture of foods specifically formulated to assist sports people in achieving specific nutritional or performance goals, and which does not include electrolyte drinks and electrolyte drink bases.

The pre-existing definition of 'one-day quantity' in clause 1 remains unchanged.

The above definitions apply throughout the Code.

The new definition of 'the Variation' in subclause 1(2) applies only to Division 4 in clause 1.

Subitem [4.5] inserts a new Division 2 heading after clause 1 as another consequence of re-structuring Standard 2.9.4.

Subitem [4.6] amends clause 6. It replaces the current prohibition on making certain representations in relation to formulated supplementary sports foods with a provision permitting health claims to be made in relation to such foods. Such a health claim must be made in accordance with Standard 1.2.7; and relate only to the specific nutritional or performance goal or goals for sports people that the food was formulated to achieve. The new clause 6 will not apply to the particular formulated supplementary sports foods covered by clause 7 to 9 of Standard 2.9.4. Existing permissions to make certain specific claims will remain.

Subitem [4.8] inserts a new Division 4 – Electrolyte drinks and Electrolyte Drink Bases into Standard 2.9.4 (clauses 10 to 17).

Clause 10 provides that new Divisions 2 and 3, which relate to formulated supplementary sports foods, do not apply to electrolyte drinks and electrolyte drink bases.

Clause 11 provides that the usual stock-in-trade provision in Standard 1.1.1 does not apply to the amendments made by the *Food Standards (Proposal P1030 – Health Claims – Formulated Supplementary Sports Foods & Electrolyte Drinks) Variation* (the Variation) in relation to electrolyte drinks and electrolyte drink bases.

Clause 12 provides for transitional arrangements during a transition period commencing on the commencement date of the Variation and ending on 18 January 2016. This will allow electrolyte drinks and electrolyte drink bases, during the transition period, to comply with the composition and labelling requirements either in the Code, which includes amendments by the Variation; or the Code as if the Variation had not commenced (but not with both).

Clause 13 provides for a stock-in-trade period, which commences on 19 January 2016 and ends on 18 January 2017. This will allow electrolyte drinks and electrolyte drink bases, during the stock-in-trade period, to comply with the composition and labelling requirements either in the Code, which includes amendments by the Variation; or the Code as if the Variation had not commenced. During the stock-in-trade period, electrolyte drinks and electrolyte drink bases may only comply with the composition and labelling requirements in the Code as if the Variation had not commenced if the food had complied with that version of the Code during the transitional period provided by clause 12. This has the effect that electrolyte drinks and electrolyte drink bases manufactured or imported during the stock-in-trade period must comply with the amended version of the Code.

Clause 14 sets out the composition requirements of electrolyte drinks and electrolyte drink bases when made up according to directions.

Subclause 14(1) requires that an electrolyte drink or electrolyte drink base, when made up according to directions, must contain no less than 10 mmol/L of sodium (according to clause 8 of Standard 1.1.1, mmol/L refers to millimole per litre).

Paragraph 14(2)(a) requires that an electrolyte drink or electrolyte drink base, when made up according to directions, must contain no less than 50 g/L and no more than 100 g/L, in total, of all of the following sugars –

- (i) dextrose;
- (ii) fructose;
- (iii) glucose syrup;
- (iv) maltodextrin; and
- (v) sucrose.

Paragraph 14(2)(b) requires that an electrolyte drink or electrolyte drink base, when made up according to directions, must not contain more than 50 g/L of fructose out of the total amount of sugars listed in paragraph 14(2)(a).

Paragraph 14(3) allows an electrolyte drink or electrolyte drink base, when made up according to directions, to contain certain minerals and salts as listed.

These requirements were previously located in clause 6 of Standard 2.6.4 and although worded slightly differently, the actual requirements remain unchanged.

Clause 15 sets out the labelling requirements of electrolyte drinks and electrolyte drink bases particularly in relation to nutrition information. Subclause 15(4) requires 'Electrolyte drink' to be used as the prescribed name for both electrolyte drinks and electrolyte drink bases. Other labelling requirements of electrolyte drinks and electrolyte drink bases were previously in clause 7 of Standard 2.6.4. However, those requirements have been amended so as to ensure that the nutrition information requirements in Standard 1.2.8 apply to the additional nutrition information requirements that are specific to electrolyte drinks and electrolyte drink bases. As requirements to declare the 'average quantity' of carbohydrate and the 'average energy content' are already set out in Standard 1.2.8; the requirement to declare 'total carbohydrate' and 'average energy value' has not been included in clause 15 of Standard 2.9.4.

Clause 16 provides for health claims to be made about electrolyte drinks and electrolyte drink bases. Such a health claim must be made in accordance with Standard 1.2.7; and only relate to the rapid replacement of fluid, carbohydrates and electrolytes lost as a result of sustained strenuous physical activity. Existing permissions to make certain specific claims remain.

Clause 17 provides for claims made in relation to the tonicity of electrolyte drinks and electrolyte drink bases. These requirements were previously in clause 8 of Standard 2.6.4 and remain unchanged.

Subitem [4.9] updates the Table of Provisions in Standard 2.9.4 to reflect the amendments made to that Standard.