

**28 May 2021**

**157-21**

## **Consultation Paper – Proposal P1030**

### **Composition and Labelling of Electrolyte Drinks**

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Proposal P1030 was prepared to review the regulation of electrolyte drinks in the *Australia New Zealand Food Standards Code*. FSANZ is seeking stakeholder views in relation to a number of issues, which will inform FSANZ's further consideration of the proposal.

For information about making a submission, visit the FSANZ [2](#).

All submissions will be published on our website. We will not publish material that we accept as confidential, 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.

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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 to receive submissions electronically via the FSANZ [website](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto: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) 9 July 2021**

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. 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](mailto:standards.management@foodstandards.gov.au).

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# Table of Contents

<b>EXECUTIVE SUMMARY .....</b>	<b>3</b>
<b>1 INTRODUCTION.....</b>	<b>5</b>
1.1 ORIGINAL PROPOSAL.....	5
1.2 MODIFIED PROPOSAL .....	5
1.3 THE CURRENT STANDARDS .....	6
1.3.1 <i>Standard 2.6.2</i> .....	6
1.3.2 <i>Standard 1.2.7</i> .....	7
1.3.3 <i>Standard 1.2.1</i> .....	7
1.3.4 <i>Standard 1.2.2</i> .....	7
1.4 INTERNATIONAL REGULATIONS.....	8
1.5 ELECTROLYTE DRINK CONSUMPTION .....	8
1.5.1 <i>Australia</i> .....	8
1.5.2 <i>New Zealand</i> .....	9
1.6 ELECTROLYTE DRINK CONSUMER RESEARCH.....	9
1.7 ELECTROLYTE DRINK MARKET.....	11
1.7.1 <i>Australia</i> .....	11
1.7.2 <i>New Zealand</i> .....	11
1.8 PROCEDURE FOR ASSESSMENT .....	12
<b>2 SUMMARY OF THE ASSESSMENT.....</b>	<b>12</b>
2.1 SUMMARY OF ISSUES RAISED IN 2014 SUBMISSIONS .....	12
2.2 RISK ASSESSMENT .....	14
2.2.1 <i>Carbohydrate Composition</i> .....	14
2.2.2 <i>Other issues</i> .....	15
2.3 RISK MANAGEMENT .....	15
2.3.1 <i>Proposed transfer to Standard 2.9.4</i> .....	15
2.3.2 <i>Definition</i> .....	16
2.3.3 <i>Minimum amount of carbohydrate g/L</i> .....	17
2.3.4 <i>Nutrition content claims</i> .....	17
2.3.5 <i>Health claims</i> .....	18
2.3.6 <i>Reference to ‘minerals’</i> .....	23
2.3.7 <i>Nutrition information requirements</i> .....	23
2.3.8 <i>Claims in relation to the tonicity of electrolyte drinks</i> .....	25
2.3.9 <i>Prescribed name</i> .....	26
2.4 RELATED ISSUES .....	26
2.4.1 <i>Electrolyte drinks and sugar sweetened beverages</i> .....	26
2.4.2 <i>Use of intense sweeteners</i> .....	27
2.4.3 <i>The use of the term ‘electrolyte’</i> .....	27
2.5 RISK COMMUNICATION.....	28
2.5.1 <i>Consultation</i> .....	28
2.5.2 <i>World Trade Organization (WTO)</i> .....	28
2.6 FSANZ ACT ASSESSMENT REQUIREMENTS .....	28
2.6.1 <i>Section 59</i> .....	28
2.6.2 <i>Subsection 18(1)</i> .....	30
2.6.3 <i>Subsection 18(2) considerations</i> .....	30
<b>3 DRAFT VARIATION .....</b>	<b>31</b>
3.1 <i>Transitional arrangements</i> .....	31
3.2 <i>Implementation and review</i> .....	31
<b>4 REFERENCES.....</b>	<b>31</b>
APPENDIX 1 – EU HEALTH CLAIMS FOR ELECTROLYTE DRINKS .....	33
ATTACHMENT A – EXAMPLE AMENDED DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD	

STANDARDS CODE .....	36
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT (EXAMPLE ONLY).....	44
ATTACHMENT C – DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE AT CALL FOR SUBMISSIONS .....	51
ATTACHMENT D – DRAFT EXPLANATORY STATEMENT AT CALL FOR SUBMISSIONS .....	58

### **Supporting document**

The following document which informed the assessment of this proposal is available on the FSANZ website.

Supporting Document 1 (SD1) – Risk Assessment Report

## Executive summary

Proposal P1030 was prepared to assess whether to permit formulated supplementary sports foods (FSSFs), electrolyte drinks and electrolyte drink bases<sup>1</sup> to carry health claims consistent with their intended purpose related to strenuous physical activity. The proposal's other aim was the transfer of the regulation of electrolyte drinks from Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drinks to Standard 2.9.4 – Formulated Supplementary Sports Foods of the Australia New Zealand Food Standards Code (the Code).

Food Standards Australia New Zealand (FSANZ) assessed the proposal in 2014 and then prepared a draft variation to the Code that would give effect to the above. FSANZ then issued a Call for Submissions (CFS) in 2014 seeking submissions on that assessment and draft variation. Submitters generally did not support the proposed changes to the Code.

In view of the above, and given relevant market developments, FSANZ now seeks stakeholders' view on a possible modified approach. That is, whereby FSANZ would – for the reasons set out in this paper – amend the draft variation prepared in 2014 to provide for the following:

- Reduce the minimum requirement for carbohydrate in electrolyte drinks from 50 g/L to 20 g/L. FSANZ's risk assessment found electrolyte drinks with lower carbohydrate (less than 5%) content have a similar effect on rehydration and exercise performance as those currently permitted in the Code. This proposed change would support the public health objective of reducing the amount of sugar in sweetened beverages.
- Reduce the maximum fructose permitted in electrolyte drinks from 50 g/L to 20 g/L, consistent with the reduced minimum carbohydrate.
- Prohibit health claims on electrolyte drinks, including self-substantiated health claims, other than for three specific claims. The three exceptions would be health claims for: hydration during strenuous physical activity; rehydration after strenuous physical activity; and hydration to maintain performance. Each claim would be required to refer to effects occurring under conditions of strenuous physical activity for a minimum time period of 60 minutes. These three health claims would be permitted on electrolyte drinks with an average osmolality of 200-340 mOsm/kg.
- Restrict nutrition content claims in relation to electrolyte drinks to those about: carbohydrate; sugar or sugars; energy; and/or any one of five substances classified as electrolytes for the purposes of nutrition content claims and nutrition labelling under Standard 2.6.2. These substances would be calcium, sodium, magnesium, potassium and chloride. Declaration of any of these substances as % Recommended Dietary Intake (%RDI) on electrolyte drinks would also be prohibited as such a declaration is not relevant to electrolyte function in these products.
- The Code would prescribe the name 'electrolyte drink' to enable identification of electrolyte drinks among similar products not regulated as electrolyte drinks.
- Amend the definition of 'electrolyte drink' to align with compositional amendments by removing the definition's reference to 'carbohydrates' and 'minerals', and removing the need for electrolyte drinks to be 'represented as'.
- The units of osmolality would be amended to 'per kilogram' for compositional requirements. However, current labelling declaration unit requirements using 'per litre' would be retained.

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<sup>1</sup> An electrolyte drink base is defined in subsection 1.1.2—3(2) of the Code as a solid or liquid which when made up, makes an electrolyte drink. Electrolyte drinks and electrolyte drink bases are collectively referred to as 'electrolyte drinks' in this Consultation paper unless stated otherwise.

- Standard 2.6.2 would continue to regulate electrolyte drinks. Moving the provisions that regulate electrolyte drinks from Standard 2.6.2 to 2.9.4 of the Code can, if required, be considered in Proposal P1010 – *Review of Formulated Supplementary Sports Foods*.

FSANZ considers that the above approach – specifically in relation to health and nutrition content claims – is consistent with its assessment of the scientific evidence (Supporting Document 1), relevant European Union (EU) claim permissions (Appendix 1) and European Food Safety Authority opinions on health claims.

Submissions to this Consultation paper – in addition to the submissions received in response to the 2014 CFS – will be used to inform FSANZ’s decision whether to approve, amend or reject the draft variation prepared in 2014 for this proposal. To assist in this regard, FSANZ has prepared a new version of the draft variation to provide an example of how FSANZ’s proposed modified approach described in this paper could be implemented in the Code.

# 1 Introduction

## 1.1 Original proposal

FSANZ originally prepared Proposal P1030 in 2014 after gazettal of the new Standard 1.2.7 – Nutrition, Health and Related claims. P1030 sought to permit formulated supplementary sports foods (FSSFs), electrolyte drinks and electrolyte drink bases<sup>2</sup> to carry health claims consistent with their intended purpose related to strenuous physical activity.

With the introduction of Standard 1.2.7 most foods were permitted to carry health claims, including claims about physical performance, providing certain claim criteria were met. However, this was not the case for FSSFs and most electrolyte drinks which, for different reasons, were limited to one or more claims in Standard 2.9.4 – Formulated supplementary sports foods or Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drinks, respectively.

Electrolyte drinks were also proposed to be transferred to Standard 2.9.4 in recognition of the product's special purpose as set out in its regulatory definition, while noting it was an preliminary step before the broader future review of Standard 2.9.4 (now being undertaken as Proposal P1010 – *Review of Formulated Supplementary Sports Foods*<sup>3,4</sup>).

In summary, P1030 was originally prepared to assess whether to:

- permit FSSF and electrolyte drinks to carry health claims consistent with their respective intended purpose and in accordance with Standard 1.2.7, noting that the minimum composition of electrolyte drinks prevented most of them from passing the Nutrient Profile Scoring Criterion (NPSC) and thus making them ineligible to make health claims
- transfer the regulation of electrolyte drinks from Standard 2.6.2 to Standard 2.9.4, given both food categories were for a similar purpose and the NPSC does not apply to special purpose foods, such as FSSFs
- make other minor amendments to improve the consistency of the regulation of electrolyte drinks in the Australia New Zealand Food Standards Code (the Code).

FSANZ assessed the proposal in 2014 and then prepared a draft variation to the Code that would give effect to the above aims or outcomes. FSANZ then issued a Call for Submissions (CFS) in 2014, seeking submissions on that assessment and draft variation. The responses to that CFS are considered below.

## 1.2 Modified proposal

The market context has changed since the release of the P1030 CFS in 2014. Some electrolyte drink manufacturers have lowered, or are seeking to lower, the carbohydrate content of their electrolyte drinks below the Code's minimum, but in so doing are unable to position these products as electrolyte drinks. A number of responses to the 2014 CFS also argued the compositional requirements were outdated and did not reflect the most up-to-date scientific evidence. In addition, the Food Ministers' Meeting<sup>5</sup> has since requested FSANZ review Standard 2.9.4 as a priority, for which FSANZ has prepared Proposal P1010.

Given these contextual changes, and after considering the submissions received in response to the 2014 CFS (see below), FSANZ is proposing to narrow the scope and direction of

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<sup>2</sup> An electrolyte drink base is defined as a solid or liquid which when made up, makes an electrolyte drink. Electrolyte drinks and electrolyte drink bases are collectively referred to as 'electrolyte drinks' in this Consultation paper unless stated otherwise.

<sup>3</sup> <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/sport-sup-action-plan>

<sup>4</sup> <https://www.foodstandards.gov.au/code/proposals/Pages/P1010.aspx>

<sup>5</sup> Formerly the Australia and New Zealand Forum on Food Regulation (the Forum)

Proposal P1030. The key matters now under consideration relate to composition and mandatory labelling requirements for electrolyte drinks as well as nutrition content and health claims made about electrolyte drinks on labels and in advertising.

Specifically, these matters include:

- a reduction in the minimum amount of carbohydrate required in electrolyte drinks based on scientific evidence and consequential changes to tonicity criteria
- prohibiting health claims on electrolyte drinks, including self-substantiated health claims, other than for three specific claims
- restricting nutrition content claims in relation to electrolyte drinks
- addressing the therapeutic nature of the existing health claim in Standard 2.6.2
- actioning FSANZ's previous commitment to consider two EU authorised health claims for 'carbohydrate electrolyte solutions'.

Several minor changes, some proposed in 2014, are further considered including the requirement for a prescribed name and removing the duplication and inconsistency in nutrition labelling requirements between Standards 1.2.8 – Nutrition Information Requirements and 2.6.2. FSANZ is proposing the regulation of electrolyte drinks remains in Standard 2.6.2 but recognises the classification of electrolyte drinks and transfer of these provisions within the Code, may be further considered under P1010.

## 1.3 The current standards

### 1.3.1 Standard 2.6.2

Standard 2.6.2 regulates packaged water and water-based beverages, including electrolyte drinks and electrolyte drink bases.

The Code defines an 'electrolyte drink' to mean *a drink formulated and represented as suitable for the rapid replacement of fluid, carbohydrates, electrolytes and minerals. An 'electrolyte drink base' is defined to mean a solid or liquid which when made up, makes an electrolyte drink.*

Sections 2.6.2—9 to 2.6.2—12 apply specifically to electrolyte drinks and electrolyte drink bases (collectively referred to below as 'electrolyte drinks').

The compositional requirements for electrolyte drinks prescribed in section 2.6.2—9 are shown in Table 1.

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

Component	Compositional Requirements
(Total) Carbohydrate (five specified sugars)	50-100 g/L
Fructose	≤50 g/L
Sodium	≥10 mmol/L

Section 2.6.2—10 permits addition of mineral salts listed in paragraphs 2.6.2—10(a)-(l) to electrolyte drinks.

Section 2.6.2—11 sets out the labelling requirements for electrolyte drinks, which relate to information about the average energy content in an electrolyte drink, the average amount of certain nutrients (carbohydrate present, and added minerals and electrolytes) in the electrolyte drink, as well as the recommended volume and frequency of use for the electrolyte drink.

Section 2.6.2—12 relates to claims made in relation to the tonicity of electrolyte drinks. Subsection 2.6.2—12(1) permits a claim that an electrolyte drink is isotonic if the drink has an average osmolality of 250–340 mOsm/L. Subsection 2.6.2—12(2) requires the declaration of osmolality to be made in mOsm/L.

Subsection 2.6.2—(12)(3) permits the label on a package of isotonic electrolyte drink to 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.*

Permission for this claim was incorporated into Standard 2.6.2 before Standard 1.2.7 came into effect.

### **1.3.2 Standard 1.2.7**

Standard 1.2.7 regulates how nutrition content and health claims on foods can be made.

Standard 1.2.7 sets out the conditions under which such claims can be made, and includes requirements for self-substantiating food-health relationships that underpin general level health claims (GLHC) and for food needing to meet the NPSC to be eligible to carry a health claim. However, the prescribed composition (specifically the prescribed minimum amount of carbohydrate) for electrolyte drinks prevents most of the drinks from carrying health claims (including self-substantiated health claims) on their labels and in advertising in accordance with Standard 1.2.7 as they are generally unable to meet the NPSC.

Standard 1.2.7 also prohibits claims that are therapeutic in nature, in other words, claims that:

- refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or
- compare a food with a good 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.

Standard 1.2.7 does not apply to claims expressly permitted elsewhere in the Code, such as the claims permitted for isotonic electrolyte drinks in Standard 2.6.2 (see section 1.2.7—6).

### **1.3.3 Standard 1.2.1**

Section 1.2.1—6 requires packaged electrolyte drinks to bear a label with the information referred to in subsection 1.2.1—8(1) (among other things) unless specific exemptions apply. The following requirements relate particularly to electrolyte drinks.

Paragraph 1.2.1—8(1)(t)(i) requires a declaration of compositional information required by section 2.6.2—11 on the labels of packaged electrolyte drinks.

Paragraph 1.2.1—8(1)(t)(ii) requires the declaration of osmolality of the electrolyte drink (as required by section 2.6.2—12) to be placed on the drink's label when a claim is made that the drink is isotonic, hypertonic or hypotonic. Section 2.6.2—12 states that the osmolality of the electrolyte drink must be declared as measured in mOsm/L.

### **1.3.4 Standard 1.2.2**

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; and which includes any additional words the Code requires to be included in the name of food.

## 1.4 International regulations

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards.

There are no Codex, European Union (EU) or United States (US) commodity standards for the regulation of electrolyte drinks or sports drinks. In the EU, electrolyte drink composition is guided by the European Food Safety Authority (EFSA) scientific opinions on carbohydrate and electrolyte criteria for health claims on 'carbohydrate electrolyte solutions' about hydration and physical performance, as summarised in their technical advice<sup>6</sup>. In the US, the American College of Sports Medicine (ACSM)<sup>7</sup> has developed a position on Exercise and Fluid Replacement regarding water and electrolyte intake during strenuous physical activity.

## 1.5 Electrolyte drink consumption

In assessing the proposal, and in considering the modified approach outlined in this paper, FSANZ had regard to data relating to the consumption of electrolyte drinks and electrolyte drink bases in Australia and New Zealand. That data was extracted by FSANZ from a number of sources as specified in this section and section 1.6 below.

### 1.5.1 Australia

The consumption of electrolyte drinks by the Australian population was determined from the average of two days of 24 hour recall data from the *2011-12 National Nutrition and Physical Activity Survey* (n=7736 respondents aged 2 years and above) (ABS, 2014) and the estimates of apparent consumption per capita of selected food based on sales of products in Australia from the *2019-2020 Apparent Consumption of Selected Foodstuffs* (ABS, 2020).

#### ***2011-12 National Nutrition and Physical Activity Survey Consumption Data***

In Australia, 2% of the survey population (aged 2 years of age and above) reported that they consumed electrolyte drinks (reported as 'sports drink') on either or both survey days, and consume a mean of 334 g/day (consumers only). High consumers of electrolyte drinks (i.e. consumption at the 90<sup>th</sup> percentile) consumed 624 g/day. In comparison, 46% of the population reported consuming water based beverages (e.g. soft drinks, cordials; excluding electrolyte drinks) across the two survey days at a mean of 413 g/day, and high consumers at 859 g/day.

For Australian children aged 2-14 years, consumption of electrolyte drinks averaged 262 g/day for consumers only. Two percent of this population group reported consuming electrolyte drinks. Due to the low number of consumers a valid consumption at the 90<sup>th</sup> percentile was not able to be derived.

The specific brand of electrolyte drink consumed by each respondent was not collected in this survey. Instead, consumption was captured under the following broad categories: sports drink ready to drink, or sports drink from dry powder. The AUSNUT 2011-13 food composition data Food Details File (FSANZ, 2016) notes that these foods capture 'All brands'. Of the two types, ready to drink sports drinks were mostly commonly reported as consumed. The sports drinks from dry powder were converted to beverages in their ready to drink form before the consumption figures above were derived.

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<sup>6</sup> <http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2015.EN-871/epdf>

<sup>7</sup> [http://journals.lww.com/acsm-msse/Fulltext/2007/02000/Exercise\\_and\\_Fluid\\_Replacement.22.aspx](http://journals.lww.com/acsm-msse/Fulltext/2007/02000/Exercise_and_Fluid_Replacement.22.aspx)

## **Apparent Consumption Data**

In the context of this Consultation paper and the data presented, apparent consumption data is a measure of the amount of food purchased from sales data, however it does not measure actual consumption as it does not account for food purchases from fast food outlets, cafes and restaurants, home grown or produced foods, wild harvested foods, or foods not consumed due to waste or storage (ABS, 2020). It is also expressed on a per person of the population basis, therefore is not reflective of consumption amounts for consumers only. The Australian Bureau of Statistics (ABS) reported that the mean daily apparent consumption of electrolyte drinks from 2019 to 2020 was 7.3 mL/person/day, which was a 0.1 mL increase from the 2018-2019 period (ABS, 2020).

### **1.5.2 New Zealand**

The consumption of electrolyte drinks by the New Zealand population was determined from National Nutrition Surveys using 24 hour recall data. One day of food consumption data for each of the NZ surveys (*2002 New Zealand National Children's Nutrition Survey* (n=3275 respondents aged 5-14 years) (Ministry of Health 2003), *2008-09 New Zealand Adult Nutrition Survey* (n=4721 respondents aged 15 years and above) (University of Otago & Ministry of Health 2011)) were used to derive consumption of electrolyte drinks.

In New Zealand, 1% of the nutrition survey population aged 15 years and above reported consuming electrolyte drinks at a mean of 768 g/day (consumers only). High consumers of electrolyte drinks (i.e. at the 90<sup>th</sup> percentile) consumed 1524 g/day. In comparison, 54% of the population reported consuming water based beverages at a mean of 591 g/day, and high consumers at 1152 g/day.

For New Zealand children aged 5-14 years, the consumption of electrolyte drinks was 355 g/day at the mean. Less than 1% of the population reported consuming electrolyte drinks. Due to the low number of consumers a valid consumption at the 90<sup>th</sup> percentile was not able to be derived.

The brand of electrolyte drink was collected in the New Zealand survey, and consumption was captured for the following brands: Powerade™, Horleys Replace™, Lucozade™ and the remaining captured under the generic categories: sports drink, from powder, sports drink from liquid concentrate. Powerade™ was reported as most commonly consumed followed by Lucozade™ for New Zealanders 15 years and above. Powerade™ was the only electrolyte drink reported as consumed by New Zealand children 5-14 years.

## **1.6 Electrolyte drink consumer research**

In April 2010, Colmar Brunton was commissioned by FSANZ to undertake research into the use of FSSFs<sup>8</sup>. The objective of this qualitative research was to investigate consumers' cognitive and behavioural approaches to purchasing and consuming these products.

Data was collected from ten focus groups undertaken in Australia and New Zealand between May and June 2010. Two focus groups comprised parents of children under 15 years of age who consumed sports drinks, and four focus groups were with adult consumers of sports drinks. The remaining four focus groups were with adult consumers of sports foods. The adult consumers were stratified across consumption frequency and whether consumption was related to physical activity or not.

The focus groups followed a standardised approach covering the following topics:

- knowledge and awareness

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<sup>8</sup> <https://www.foodstandards.gov.au/publications/Pages/Consumer-research-investigating-the-use-of-sports-foods.aspx>

- perceptions and attitudes
- purchase and consumption behaviours.

Research participants in Australia and New Zealand had discrete definitions of what a 'sports drink' was, and this was generally consistent with what an electrolyte drink is. Consumers generally differentiated sports drinks from energy drinks (formulated caffeinated beverages) and vitamins waters (formulated beverages). Brands recognised as sports drinks included Powerade, Gatorade, Staminade, Lucozade and, in New Zealand, Mizone.

Research participants were very aware of electrolyte drinks through marketing and prominent displays at many types of retail outlet. There was a feeling that the products were ubiquitous and stood out from other products due to their brightly coloured liquids and packaging.

This research found that adults, both sedentary and exercising adults, and children report consuming electrolyte drinks. Consumption of electrolyte drinks by children was reportedly driven by both parents and children, with evidence suggesting that parents and children perceived electrolyte drinks to be suitable and beneficial based on the recommendations of sports coaches and/or marketing and promotions by elite athletes. There was some agreement among parents of children who consume electrolyte drinks that marketing targets young children through to late teens.

Electrolyte drink consumption was driven by a range of exercise, non-exercise and hydration related reasons, including sports performance and recovery, avoidance of muscle cramps, playing outside in the heat, taste and as a soft drink substitute. There were differences between those considered 'active' or 'sedentary' based on reported level of physical activity. Active participants reported they primarily consumed electrolyte drinks for intense and moderate exercise or recreational activities and reported that health benefits exist only during or immediately after exercise. Active participants generally agreed that electrolyte drinks were for physical activity and therefore should not be consumed by sedentary people. However, some active participants did report consuming electrolyte drinks when 'on the run', thirsty, out in the sun or needing energy because they were feeling flat or lethargic.

In both Australia and New Zealand, sedentary participants did not believe that electrolyte drinks should be confined to sporting activities; seeing electrolyte drinks as a way to hydrate and deliver extra energy. Although the reasons for consumption may have originally been exercise related, some continued consumption was subsequently related to taste, energy, stamina (e.g. for an exam) and quenching thirst. There was also some evidence that some consumers saw electrolyte drinks as an alternative to soft drinks when purchasing for thirst related reasons as they viewed electrolyte drinks to be healthier than soft drinks. Further, participants in both countries felt that electrolyte drink marketing was aimed towards the general public. Similar to the views of parents, the adult focus group participants also reported that athletic endorsement can enhance credibility and a belief of efficacy for electrolyte drinks.

The commissioned research provides evidence that:

- 'Non-target' consumers are consuming electrolyte drinks, including children and sedentary adults
- Some consumers report to use electrolyte drinks for the rapid replacement of fluid, carbohydrates, electrolytes and minerals
- Some adults and children are reportedly consuming electrolyte drinks for reasons not related to exercise, including for taste and as a sugar-sweetened beverage substitute
- Athletic endorsement/marketing and sporting coach recommendations are seen to create a belief of electrolyte drink efficacy and suitability – in both children and adults

- Some consumers see electrolyte drinks as an alternative to soft drinks when purchasing for thirst or lethargy related reasons as they view electrolyte drinks to be healthier than soft drinks.

## 1.7 Electrolyte drink market

### 1.7.1 Australia

Market share data were provided by/sourced from the food industry. These data indicate that electrolyte drinks accounted for 3% total soft drink market share in 2019. Sales analysis indicate a 4% increase in off-trade sales in 2017.

The Coca-Cola Company's product Powerade™ and PepsiCo's product Gatorade™ hold the majority of the electrolyte drink market, collectively accounting for 83.5% (Global Data, 2020). Further to this, Coca-Cola Amatil continues to dominate the category with a 52% share of off-trade value sales (Euromonitor, 2018).

Since 2011, when the nutrition survey data were collected, there has been a 30% increase in the volume of electrolyte drinks sold. This more likely indicates an increase in the proportion of consumers rather than an increase in consumers' daily consumption. However, there is uncertainty associated with this assumption given the absence of recent survey data for the population.

Industry data for Australia (iRi, 2020) from the Australian Beverages Council Ltd indicates that the total retail litres scan of sports drinks increased by 3% from 2018 to 2020 with total Powerade™ sports drinks accounting for 49.7% of total retail litre shares in 2020.

In 2020, sports drinks accounted for \$266,218,000 of the total retail dollars scan, of which total Powerade™ sports drinks contributed 53.8%, total Gatorade™ sports drinks contributed 30.6% and total Maximus™ sports drinks contributed 13.0%. With the addition to total retail of sports drinks purchased from or sold for use in bakeries, news agents, food outlets etc., the 2020 sports drinks market accounted for 104,270,000 L and \$359,359,000 (iRi, 2020).

The above market share data defines 'sports drinks' as 'beverages that are sold within a particular area of the supermarket or retail store'. Examples of products that are included within this category and in the data provided include Powerade Isotonic ION4™, Powerade Zero™, Powerade™ powders, Gatorade™, Gatorade™ powder, Gatorade™ enhanced formula powder, Gatorade Fierce™, Maximus™ and Mizone Sport™. This excludes products such as G-Active™ and other enhanced/functional waters as they are usually in a separate section of the supermarket and are classified in the Code separately under Formulated Beverages. 'Sports drinks' is a loose term that is used to describe beverages that are consumed at similar occasions and appear to have similar properties and are linked with sport/exercise. There is no specific definition and it is decided by both the retailer and the manufacturer as to where a product is placed in store. The definition does not necessarily meet the definition of 'electrolyte drink' as defined in the Code (Standard 2.6.2).

### 1.7.2 New Zealand

Market share data for New Zealand indicate that electrolyte drinks account for 3% of the total soft drink market share in 2017. Sales analysis indicates a 1% decline in Off-trade sales. The Coca-Cola Company's Powerade™ holds the dominant market share in this category, accounting for just over 60% of the retail value share in 2017 (Global Data, 2020). Sales data indicate that since the time of the children's national nutrition survey in 2002, there has been a 54% increase in sales volume, and a 33% increase since the 2008 Adult's Nutrition Survey. Similar to Australia, this more likely indicates an increase in the proportion of consumers since the time of the surveys (Euromonitor International, 2018).

## 1.8 Procedure for assessment

The proposal is being assessed under the General Procedure.

As mentioned above, FSANZ assessed the proposal in 2014 and then prepared a draft variation to the Code that would give effect to the above aims or outcomes. FSANZ then issued a CFS in 2014, seeking submissions on that assessment and draft variation.

FSANZ is now required to decide whether to approve, amend or reject the draft variation that it prepared in 2014. The matters listed in sections 18 and 59 of the FSANZ Act remain relevant to that decision.

After considering the submissions received, and for the reasons set out in this paper, FSANZ's preliminary view is that amendment of the draft variation may be warranted. The purpose of this Consultation paper is to seek public submissions on these possible amendments and their rationale. The submissions received, together with those received by FSANZ in 2014, will inform FSANZ's decision on whether to approve, amend or reject the draft variation. To assist in this regard, FSANZ has prepared a new version of the draft variation to provide an example of how FSANZ's proposed modified approach described in this paper could be implemented in the Code (see 'Example amended draft variation' at Attachment A).

## 2 Summary of the assessment

P1030 was reassessed following FSANZ's consideration of submissions received during the call for submissions (CFS) period in 2014 and in light of market developments since that time.

### 2.1 Summary of issues raised in 2014 submissions

FSANZ received 39 responses to the P1030 2014 CFS from the following stakeholder groups:

Submitter group	No of submissions
Industry	10
Public health	11
Health professionals & academics	7
Consumer groups & individuals	5
Jurisdictions	5
Government, other	1

The consultation period closed on 30 September 2014.

Table 2 below provides a high level summary of issues originally relevant to P1030. As stated above, FSANZ is no longer proposing that electrolyte drinks be regulated by Standard 2.9.4. A more detailed discussion of the risk management of relevant issues including those raised by submitters is given in Section 2.3 of this Consultation paper.

**Table 2: High level summary of issues**

ISSUE	SUBMITTER(S)	FSANZ RESPONSE
<b>Regulatory</b>		
Mixed support for transfer of electrolyte drinks to Standard 2.9.4. Supported because electrolyte drinks are special	Jurisdictions, Public health, Health	After considering submitters' responses, FSANZ proposes to retain the regulation of electrolyte

ISSUE	SUBMITTER(S)	FSANZ RESPONSE
purpose food (SPF); but not supported as a SPF because of exemption from Health Star Rating graphics, and inconsistency with current marketing and promotion approaches.	professionals & academics	drinks in Standard 2.6.2. Moving the provisions that regulate electrolyte drinks from Standard 2.6.2 to 2.9.4 can, if required, be considered further in light of the outcome of the review of Standard 2.9.4 (P1010).
Clarify whether caffeine can be added to electrolyte drinks, as it is specifically prohibited in formulated beverages which regulates similarly presented no sugar products such as active waters.	Jurisdictions	Proposal P1056, to commence mid-2021, will review the permissions for caffeine generally, including the addition of caffeine to sports foods (and electrolyte drinks); and consider the risk that caffeine poses to sensitive sub-populations.
<b>Scientific Rigor</b>		
Current scientific evidence should be reviewed and applied as appropriate to the electrolyte drink standard to both the compositional requirements and substantiation of any permitted claims to support the food-health relationship and to ensure transparency.	Jurisdictions, Public health, Health professionals	FSANZ reviewed the available scientific evidence following the release of the CFS and receipt of submissions. For the reasons set out in this paper, FSANZ has now modified the approach and now includes changes to carbohydrate composition, and a prohibition and restrictions on claims that may be made about electrolyte drinks. The evidence underpinning the proposed changes is given in Sections 2.2. and 2.3 of this Consultation paper and SD1.
<b>Public Health</b>		
<p>The proposal is inconsistent with the primary objective of the FSANZ Act and requires further assessment.</p> <p>Electrolyte drinks are sugar sweetened beverages and their consumption is associated with adverse health outcomes including obesity, dental erosion and increased blood pressure.</p>	Jurisdictions, Public health, Health professionals, academics, consumer groups and individuals	The consumption of electrolyte drinks represents a small proportion of the total consumption of sugar sweetened beverages. Nonetheless, FSANZ recognises sugar sweetened beverages are a contributing factor to adverse health outcomes. The proposed amendment to reduce the minimum carbohydrate (sugars) requirement from 5% to 2% will allow manufacturers to provide consumers with healthier electrolyte drink options than those currently available which means a reduced sugar intake for those consumers who opt for the lower sugar product. In addition, the proposed prohibition on health claims, other than three specific claims which will require a reference to effects occurring during strenuous physical activity for a minimum time period will better assist consumers to make informed choices by providing clarity for both

ISSUE	SUBMITTER(S)	FSANZ RESPONSE
		target and non-target consumers to more clearly identify both the intended purpose and the intended end user of these products. These amendments are considered consistent with FSANZ's objective and reflect current public health policy.
<p>Permitting health claims on electrolyte drinks is viewed as promoting consumption of electrolyte drinks, will mislead consumers into thinking that such claims are a healthier option than other sugar sweetened beverages, and is inconsistent with national population-based nutrition guidelines and general healthy eating advice.</p> <p>Health claims on electrolyte drinks (will) create a 'health halo' effect by (further) validating the misconception of the health benefits of electrolyte drinks with consumers extending the claim beyond its intended purpose.</p> <p>Limited benefit and potential risk of misleading health claims that do not support informed consumer choice.</p>	Public health professionals, academics, consumer advocacy groups and individuals	<p>A health claim has specifically been permitted for electrolyte drinks since the early 1990s.</p> <p>Based on submitter responses and further consideration of the evidence, FSANZ is considering amending the draft variation to prohibit health claims on electrolyte drinks other than three limited claims, and to require those limited claims to refer to the effects occurring under conditions of strenuous physical activity for a minimum time period of 60 minutes to assist consumers to make better informed choices.</p>
<b>Consumption</b>		
The marketing of electrolyte drinks to the general population and the availability and ease of access through sales at convenience stores, petrol stations and supermarkets, promotes inappropriate use by consumers (non-athletes, particularly children) and high levels of consumption which will increase.	Public Health, Consumer and Public Health Groups	Proposed reduction in minimum carbohydrate levels provides for lower carbohydrate options and the reference to strenuous physical activity for a minimum time period of 60 minutes in any claims is expected to guide consumers to appropriate use.

## 2.2 Risk assessment

### 2.2.1 Carbohydrate Composition

Intense physical exercise leads to sweating in order to dissipate heat and reduce body temperature to normal levels. Sweating results in a loss of body water, sodium and, to a lesser extent, other minerals including potassium, calcium and magnesium. Physiological responses to dehydration include increased cardiovascular strain, an inability to thermoregulate and at high levels results in impaired mental function.

Dehydration as well as a decrease in the body's carbohydrate reserves can impair physical performance. Consumption of electrolyte drinks during and after intense exercise aids in rehydration and maintaining physical performance. Research on electrolyte drinks has primarily focused on those with a carbohydrate content of 6 to 18%. Standard 2.6.2 currently requires an electrolyte drink to contain 5 to 10% carbohydrate.

The purpose of this review was to determine if lower carbohydrate (less than 5%) electrolyte drinks have a similar effect on rehydration and exercise performance as those that are currently permitted in the Code.

Seven randomised crossover studies were included in the body of evidence for the effect of lower carbohydrate electrolyte drinks on rehydration compared to electrolyte drinks with the currently permitted levels of carbohydrate. Subjects exercised for approximately one hour or until a body weight loss of approximately 2% was achieved. In general, beverages were consumed following exercise and the effects on recovery from dehydration were considered. However, one study observed the effects of electrolyte drinks on preventing dehydration when drinks were consumed during exercise.

Four randomised crossover studies were considered as evidence for the effect of lower carbohydrate electrolyte drinks on exercise performance compared to electrolyte drinks with higher carbohydrate concentrations. Participants exercised for between 60 and 120 minutes while consuming electrolyte drinks with a carbohydrate content of 2 to 10%. Exercise performance was measured in terms of time to exhaustion or time trial following exercise of approximately one hour.

A number of limitations in study design were identified in the body of evidence including the lack of blinding of participants and investigators in some studies, small sample size, as well as the reliability of hydration markers which may have made differences in drink composition difficult to detect.

This assessment concluded that based on the available evidence no clear difference between lower carbohydrate electrolyte drinks and those that are currently permitted in the Code were observed in terms of benefit on rehydration or enhancing exercise performance when consumed during or on completion of sustained exercise (at least 60 minutes or 2% body weight loss).

## **2.2.2 Other issues**

FSANZ has identified a number of other issues that relate to both the consumption and marketing of electrolyte drinks including nutrition content and health claims, nutrition information requirements, terminology and the consumption of sugar sweetened beverages. These issues have been addressed in sections 2.3.4, 2.3.5, 2.3.7, 2.3.9, 2.4 below.

## **2.3 Risk management**

### **2.3.1 Proposed transfer to Standard 2.9.4**

#### ***2.3.1.1 Approach in 2014 Call for submissions***

FSANZ originally proposed to transfer the regulation of electrolyte drinks from Standard 2.6.2, a general commodity standard, to a special purpose food standard, Standard 2.9.4 (see drafting at Attachment C). This was to both recognise and emphasise the product's special purpose in accordance with its regulatory definition while noting it was a preliminary step prior to the review of Standard 2.9.4.

Submitters were mixed in their support for the transfer citing either consistency with electrolyte drinks as a special purpose food; or if a special purpose food, it would exempt electrolyte drinks from Health Star Rating graphics and be inconsistent with current marketing and promotion approaches. Two jurisdictions supported the transfer of electrolyte drink regulations to Standard 2.9.4. Some jurisdictions questioned why the proposal was proceeding ahead of a comprehensive review of Standard 2.9.4 that incorporated electrolyte drinks. All jurisdictions commented that any proposed regulatory changes should be underpinned by a robust scientific evidence base. One jurisdiction also noted the transfer of electrolyte drink regulation to Standard 2.9.4 would not reflect the actual range of population

usage.

### **2.3.1.2 Proposed approach**

FSANZ is proposing to limit P1030 now to the composition and labelling of electrolyte drinks within Standard 2.6.2. Any transfer of these provisions to Standard 2.9.4 and the reclassification of electrolyte drinks as special purpose foods may be further considered as part of the review of sports foods (P1010).

## **2.3.2 Definition**

### **2.3.2.1 Approach in 2014 Call for submissions**

The current definition of 'electrolyte drink' in section 1.1.2—3 is:

**electrolyte drink** means a drink formulated and represented as suitable for the rapid replacement of fluid, carbohydrates, electrolytes and minerals.

The revised definition in 2014 was proposed as:

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

At the time, FSANZ considered the requirement for electrolyte drinks to be 'represented as' relied on voluntary labelling including health claims which had become superfluous. The proposed revised definition strengthened the association of consumption of electrolyte drinks with their intended purpose for use in relation to sustained strenuous physical activity.

Also, FSANZ proposed removing the reference to minerals because there is no mandatory compositional requirement to include minerals, other than sodium, which can also be considered as an electrolyte and is considered as such in certain tables in Schedule S29 – Special purpose foods.

Government submitters supported the revised definition including those who sought further alignment between the definition and the permitted claim. One industry submitter opposed omitting 'represented as' because enforcement would be easier for regulators based on labelling representations rather the compositional requirements.

A few submitters sought definitions of particular terms in the revised definition for: sustained strenuous exercise, rapid replacement, and electrolyte (and in the 2.9.4 context – no longer considered – sports person, and achieving specific nutritional or performance goals).

### **2.3.2.2 Proposed new approach**

FSANZ is proposing to make further edits to the definition proposed in 2014 to reflect the additional proposed compositional and labelling changes, as follows:

**electrolyte drink** means a drink formulated for the rapid replacement of fluid and electrolytes during or after 60 minutes or more of sustained strenuous physical activity.

FSANZ proposes to retain the amendment to the definition proposed in 2014 in relation to only referring to 'formulated for' rather than including 'represented as', because 'formulated for' provides for alignment with the compositional requirements in Standard 2.6.2. Also, no enforcement agencies expressed concern or provided evidence in submissions about any inability to enforce the Code if the definition referred to only 'formulated for'.

Additionally, FSANZ notes the Code requires that any requirement in Standard 2.6.2 must be met for any sale in which a purchaser is likely to assume that the food being sold was an electrolyte drink (sections 2.6.2—11(1) and 1.1.1—13). This would apply in addition to the general approach that any food meeting the definition of 'electrolyte drink' would have to meet the requirements for electrolyte drinks in Standard 2.6.2.

FSANZ is also proposing to reduce the minimum carbohydrate content of an electrolyte drink (see Section 2.3.3 of this Consultation paper) and, therefore considers the electrolyte drink definition should no longer give prominence to replacement of carbohydrate. The 2014 removal of minerals from the definition is maintained.

To address submitter requests to describe what is meant by sustained strenuous physical activity, FSANZ has included a minimum time period of 60 minutes to explain the term *sustained* based on scientific evidence in SD1. In this context, definitions of other terms such as *strenuous* and *rapid replacement*, have been left to their ordinary meanings.

No change is proposed to the definition of an electrolyte drink base (i.e. *a solid or liquid which, when made up, makes an electrolyte drink.*).

### **2.3.3 Minimum amount of carbohydrate g/L**

#### **2.3.3.1 Approach in 2014 Call for submissions**

The 2014 proposal did not consider changing the minimum level of carbohydrate in electrolyte drinks. One industry submitter recommended a lower carbohydrate threshold to encompass hypotonic beverages. Jurisdictions also highlighted the importance of reviewing the current scientific literature to determine the optimal electrolyte drink composition.

#### **2.3.3.2 Proposed new approach**

Following submitter comments and representations from the beverage industry, on the limitation of the prescribed minimum 50 g/L carbohydrate content of electrolyte drinks (see Section 1.2 of this Consultation paper), together with recent market developments, FSANZ has reviewed the scientific evidence to determine if lower carbohydrate (<50 g/L) electrolyte drinks had a similar effect on re/hydration and physical performance as those currently permitted by Standard 2.6.2 (50-100 g/L).

On the basis of the risk assessment conclusion (Section 2.2 of this Consultation paper and SD1) that no clear difference exists between electrolyte drinks with 20-50 g/L carbohydrate compared with 50-100 g/L carbohydrate in relation to rehydration or exercise performance when consumed during or after sustained exercise ( $\geq 60$  minutes or 2% body weight loss), FSANZ proposes to lower the minimum permitted carbohydrate for electrolyte drinks to 20 g/L while retaining the maximum carbohydrate at 100 g/L. This minimum also corresponds with the EU minimum condition for health claims on electrolyte drinks (see Section 2.3.5.2.2 of this Consultation paper).

Consistent with a reduced minimum carbohydrate of 20 g/L, the maximum fructose of 50 g/L which currently corresponds to the minimum carbohydrate, also needs to be reduced to 20 g/L. FSANZ is advised that fructose is seldom used as an ingredient in electrolyte drinks but when so, its content is below 20 g/L.

### **2.3.4 Nutrition content claims**

#### **2.3.4.1 Approach in 2014 Call for submissions**

Nutrition content claims about electrolyte drinks can currently be made in accordance with Standard 1.2.7. No changes were proposed to the regulation of nutrition content claims for electrolyte drinks in 2014.

One submitter commented that nutrition content claims (and health claims) have been used by food companies as marketing tools to increase sales and market share. Another submitter suggested including a pre-approved nutrition content claim for electrolytes to proactively clarify the use of the term 'electrolyte' on products and set appropriate conditions for its use.

### **2.3.4.2 Proposed new approach**

FSANZ now proposes to prohibit all nutrition content claims about electrolyte drinks except for nutrition content claims about carbohydrate, sugar or sugars, energy and certain 'prescribed electrolytes' (see below).

The rationale for this approach is to limit nutrition content claims to those associated with the intended purpose and regulatory composition of electrolyte drinks. This would reduce the potential for claims to mislead consumers about the purpose and place of electrolyte drinks in the diet and aligns with the approach for health claims (see Section 2.3.5 of this Consultation paper). The permission for sugar/s claims would also allow for 'reduced sugar' type claims, noting the proposed approach to reduce the minimum carbohydrate content in electrolyte drinks. Nutrition content claims about carbohydrate, sugar/s and energy would have to comply with the applicable conditions in Standard 1.2.7 and Schedule 4.

#### **2.3.4.2.1 'Prescribed electrolytes'**

FSANZ proposes amending the draft variation to list five electrolytes (calcium, sodium, magnesium, potassium and chloride) as 'prescribed electrolytes'. This is because some of the substances listed as 'prescribed electrolytes' for the purposes of electrolyte drinks are also 'minerals' for the purposes of requirements elsewhere in the Code.

In the example amended draft variation, a nutrition content claim would be able to be made about the presence of these prescribed electrolytes by referring to electrolytes generally, for example, 'contains electrolytes' or to the individual prescribed electrolyte(s) present in the drink, for example, 'contains the electrolytes: calcium and sodium'. For a nutrition content claim about individual prescribed electrolytes, the claim would also have to state that they are 'electrolytes' as in the above example. This is intended to inform consumers about their function in the body as electrolytes rather than as minerals (see Section 2.3.7.2 below for the proposed requirements for the declarations of electrolytes in the nutrition information panel).

For nutrition content claims about prescribed electrolytes, it is proposed that the conditions in Standard 1.2.7 and Schedule 4 for nutrition content claims would not apply to these claims. The conditions for magnesium and calcium claims as minerals in Schedule 4 are not considered appropriate as these are based on a recommended dietary intake (RDI) which is not relevant to the function of magnesium or calcium as an electrolyte in electrolyte drinks. Similarly, the conditions in Schedule 4 for nutrition content claims about sodium are not applicable as they are for the purposes of low or lower sodium claims rather than the function of sodium as an electrolyte. No other claim conditions for composition are proposed, which is consistent with the current approach for nutrition content claims about potassium and chloride in the Code.

### **2.3.5 Health claims**

#### **2.3.5.1 Approach in 2014 Call for submissions**

FSANZ proposed that electrolyte drinks be permitted to carry health claims relating to their intended purpose (i.e. to help with rapid replacement of fluid, carbohydrate and electrolytes) in accordance with the requirements in Standard 1.2.7, which allowed for self-substantiated health claims.

As the approach was to incorporate the regulation of electrolyte drinks into Standard 2.9.4, electrolyte drinks carrying health claims were not required to meet the NPSC, consistent with the approach for special purpose foods. Such foods are exempt from the requirement to meet the NPSC as they are specially formulated for specific dietary purposes and must meet certain prescribed compositional requirements related to these purposes.

The existing permitted claim referring to availability of energy and preventing or treating mild dehydration in subsection 2.6.2—12(3) for isotonic electrolyte drinks was also proposed to be retained in 2014.

Some submitters supported the proposed approach or elements of the proposed approach, whereas other submitters did not, as outlined below. A number of submitters commented about inconsistency of the proposed approach with the Policy Guideline for Nutrition, Health and Related Claims<sup>9</sup>.

Some submitters were concerned that permitting health claims on electrolyte drinks would give them a 'health halo' and promote their consumption inconsistent with national nutrition guidelines. Another concern was that health claims on electrolyte drinks would lead to over-consumption of sugar by misleading people into thinking electrolyte drinks were beneficial to anyone regardless of their level of physical activity, or that electrolyte drinks were part of a healthy diet. It was stated that athletes who benefit from using electrolyte drinks do not require further information in the form of health claims as they receive information from other sources. Some submitters considered a stronger rationale was required to exempt electrolyte drinks from meeting the NPSC to carry a health claim.

Conversely, one submitter did not support the proposed restriction on the scope of health claims permitted as this would unnecessarily restrict innovation and the growth of scientific evidence regarding the application of electrolyte drinks in sports performance. The restriction was recommended to be removed and to instead rely on the evidence requirements in Standard 1.2.7 to support evidence-based claims.

Some submitters considered the current permitted claim should be reviewed against current evidence and, if considered appropriate, to be included in Standard 1.2.7.

One submitter noted there was no requirement for a dietary context statement to be included in the wording of the claims currently permitted under Standard 2.6.2, which is inconsistent with the approach in Standard 1.2.7. Another considered the claims should state the target consumer and exercise conditions to which the stated performance benefit applies and that a definition of sustained strenuous exercise is required and should appear on the label and in advertising.

### **2.3.5.2 Proposed new approach**

FSANZ is proposing to amend the claim permission in subsection 2.6.2—12(3), as detailed in the subsections below. In summary, FSANZ is proposing to prohibit health claims on electrolyte drinks, including self-substantiated health claims, other than for three specific claims. The three exceptions would be health claims for: hydration during strenuous physical activity; rehydration after strenuous physical activity; and hydration to maintain performance. Each claim would be required to refer to effects occurring under conditions of strenuous physical activity for a minimum time period of 60 minutes. These three health claims would be permitted on electrolyte drinks with an average osmolality of 200-340 mOsm/kg.

The rationale for this approach is to reduce the potential for non-target consumers to be misled about the benefits of electrolyte drinks and their place in the diet. The proposed approach would result in a similar situation to the current situation whereby most electrolyte drinks would not be able to make health claims according to Standard 1.2.7 (as they do not meet the NPSC), but would provide for specific relevant claims associated with the purpose of electrolyte drinks. FSANZ proposes that the requirements in Standard 1.2.7 would not apply to these claims, however specific wording requirements regarding the target population are included (as detailed in Section 2.3.5.2.2 of this Consultation paper).

The overall approach for health claims about electrolyte drinks will be reconsidered in the broader context of the regulation of sports foods under P1010.

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<sup>9</sup> <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-Nutrition-Health-and-Related-Claims>

#### 2.3.5.2.1 Permitted health claims on electrolyte drinks

The current claim permission in subsection 2.6.2—12(3) is:

*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.*

It is noted that the wording of the current claim is not prescribed, but is ‘to the effect’ *that the product is designed to...* which gives manufacturers some latitude in composing their claims according to the Code’s intent. This level of prescription is the same as that for health claims regulated by Standard 1.2.7.

The proposed reduction in minimum carbohydrate content while retaining the current maximum carbohydrate level increases the range of carbohydrate permitted in electrolyte drinks. Consistent with this compositional change and, based on the assessment of scientific evidence, FSANZ proposes to amend the permitted claim and to extend its scope to apply to both isotonic and hypotonic electrolyte drinks, for various reasons explained below. The proposed amended claim permission would permit three specific health claims for isotonic and hypotonic electrolyte drinks.

#### 2.3.5.2.2 Reasons for the proposed permitted health claims

##### **EU health claims for electrolyte drinks**

Under P293 – Nutrition, health and related claims, several food health relationships based on EU-authorised health claims were incorporated into the new Standard 1.2.7, but two such claims relating to carbohydrate electrolyte solutions were deferred for further consideration in this proposal<sup>10</sup>.

The two EU authorised health claims relating to electrolyte drinks are –

Carbohydrate electrolyte solutions:

- enhance the absorption of water during physical exercise
- contribute to the maintenance of endurance performance during prolonged endurance exercise.

The same compositional criteria apply to each claim. Since these criteria specify a minimum carbohydrate of only 20 g/L, FSANZ assumes the second claim – *contribution to the maintenance of endurance performance* manifests through maintenance of hydration rather than through the supply of carbohydrate as a source of energy. The scientific rationale and the conditions for these two health claims are given in Appendix 1 to this Consultation paper.

##### **FSANZ and EFSA evidence assessments as basis of claim effects**

Both sources of evidence reviewed by FSANZ and by EFSA were considered by FSANZ before proposing amendment of the current claim permission because they both reviewed the relationships between consumption of electrolyte drinks and hydration/water absorption, and electrolyte drinks and physical performance.

The risk assessment undertaken by FSANZ, outlined in Section 2.2 of this Consultation paper and in SD1, reviewed the comparative difference between electrolyte drinks above and below 5% carbohydrate with respect to hydration and performance, whereas EFSA reviewed evidence for these two health effects from consumption of electrolyte drinks containing ~1.9-8.4% carbohydrate. Both FSANZ and EFSA reviewed the evidence under conditions of

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<sup>10</sup> <https://www.foodstandards.gov.au/industry/labelling/Pages/Outcomes-from-consideration-of-European-Union-authorised-health-claims.aspx>

strenuous exercise for 60 minutes or more, but neither undertook a full systematic review. Although both reviews did not have precisely the same aim, this proposal brings together the findings of the assessment undertaken by FSANZ (see SD1) and the EU health claim reviews as the evidence base for amending the current claim permission for electrolyte drinks.

As mentioned above, the proposed reduction in minimum carbohydrate content extends the range of electrolyte drinks to include hypotonic electrolyte drinks. This is because:

- FSANZ found no difference between electrolyte drinks having the current required carbohydrate levels or a lower minimum carbohydrate in relation to hydration and consequent performance effects (SD1); and
- the same lower minimum carbohydrate content applies to both EU claims about water absorption and performance.

The current claim permission in Standard 2.6.2 is therefore proposed to be replaced with a permission for three health claims: for hydration, for rehydration, and hydration to maintain performance. All three health claims would be applicable to isotonic and hypotonic electrolyte drinks.

### ***Permitted health claims***

This subsection describes the particular changes proposed to amend the current claim permission (see Section 2.3.5.2.1 of this Consultation paper) and reasons for the several inclusions and deletions.

#### *Proposed inclusions, changes and deletions*

- (i) **Delete** *promote the availability of energy* because the minimum energy from carbohydrate content is proposed to be reduced. Also electrolyte drinks would continue to be permitted to carry nutrition content claims about energy.
- (ii) **Change** *prevent or treat mild dehydration*. The claim's original language was devised in the early 1990s and includes words that imply a therapeutic intent. The Policy Guideline on Nutrition, Health and Related claims states that therapeutic claims should not be permitted and the more recent Standard 1.2.7 requires claims regulated by that Standard not to refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition (section 1.2.7—8). The use of *prevent or treat* in the claim permission is inconsistent with the policy guidance and the intent of Standard 1.2.7 and is therefore proposed to be removed.

*Dehydration* can be readily modified to re/hydration. FSANZ has not used *water absorption* from the EU claim because of possible confusion with a water beverage which is suitable for hydration.

- (iii) **Adopt** *contribute to the maintenance of performance* from the EU performance claim.
- (iv) **Retain** *strenuous exercise* but replace *exercise* by *physical activity* to allow for a wider target group (including those who exercise).
- (v) **Replace** *sustained* (similar to *endurance* in EU performance claim) with *60 minutes or more* to quantify the minimum amount of time needed for strenuous activity to provide guidance on the appropriate use of the product to both target and non-target consumers.
- (vi) **Replace** *may occur as a result of* with a time element *during and after* to indicate the periods relevant to the intended effect.

These proposed inclusions and deletions would have the effect of permitting the following health claims about electrolyte drinks to be made:

*Rapid rehydration in association with words to the effect of 'after at least 60 minutes or more of strenuous physical activity'.*

*Rapid hydration in association with words to the effect of 'during at least 60 minutes or more of strenuous physical activity'.*

*Contribution to the maintenance of performance by rapid hydration in association with words to the effect of 'during at least 60 minutes or more of strenuous physical activity'.*

### **Claim condition – what the claim is about**

Certain conditions for use of these health claims would apply.

Claims would be permitted only about the three health effects listed above, i.e. rapid rehydration, rapid hydration, or contribution to the maintenance of performance by rapid hydration. The maintenance of performance is expressed in the context of rapid hydration consistent with the assessment of FSANZ (SD1) and the EU (Appendix 1).

FSANZ considers it important that all such claims indicate that it is relevant only to individuals undertaking strenuous physical activity for a time period of at least 60 minutes. This is as much to identify the non-target group as to identify the target group. Similar to Standard 1.2.7, the wording of the claims based on the amended permission is not prescribed, however the time period of '60 minutes or more' must be expressed as a quantifiable amount of time, for example, 60 minutes or one hour.

### **Claim condition – osmolality units and range**

The claim permission continues to have a prescribed osmolality range as a condition of use.

FSANZ acknowledges the units for osmolality are technically /kg and not /L so it is proposed to amend the units to /kg for all compositional requirements.

With the proposed reduction of minimum carbohydrate for electrolyte drinks, the lower bound of the average osmolality range for permitted claims also needs to be reduced to permit hypotonic and isotonic electrolyte drinks to carry the permitted health claims. The osmolality range for the two EU claims is 200–330 mOsm/kg water, the lower bound of which corresponds to a minimum carbohydrate of ~20 g/L. Therefore the lower osmolality bound would be reduced to 200 mOsm/kg while retaining the maximum osmolality for isotonic electrolyte drinks of 340 mOsm/kg. The osmolality range of an electrolyte drink permitted to have health claims is thus expanded to 200–340 mOsm/kg.

Table 3 compares the proposed amended claim permission and electrolyte drink compositional requirements with the two EU authorised health claims, indicating the similarity of the wording and conditions.

**Table 3: Comparison of proposed revised permitted claim with EU claims**

<b>Element</b>	<b>Proposed revisions to electrolyte drinks</b>	<b>EU health claims</b>
Product category	electrolyte drinks	carbohydrate-electrolyte solutions
Claim – hydration	rapidly (hydrate during) (rehydrate after) 60 minutes or more of strenuous physical activity.	enhance the absorption of water during physical exercise

<b>Element</b>	<b>Proposed revisions to electrolyte drinks</b>	<b>EU health claims</b>
Claim – hydration to maintain performance	contribute to maintenance of performance by rapid hydration during 60 minutes or more of strenuous physical activity	contribute to the maintenance of endurance performance during prolonged endurance exercise
carbohydrate	20–100 g/L carbohydrate from dextrose, glucose syrup, maltodextrin, sucrose, fructose.  No more than 20 g/L fructose	80–350 kcal/L from carbohydrates [≅19.1 – 83.6 g/L carbohydrate], and  at least 75 % energy should be derived from carbohydrates which induce a high glycaemic response, such as glucose, glucose polymers and sucrose.
Sodium	No less than 10 mmol/L sodium (no change)	20–50 mmol/L (460–1,150 mg/L) sodium
Osmolality (health claim condition)	Average osmolality 200–340 mOsm/kg	Osmolality 200–330 mOsm/kg water

### **2.3.6 Reference to ‘minerals’**

#### **2.3.6.1 Approach in 2014 Call for submissions**

Existing section 2.6.2—10 contains permission to add various ‘minerals’ (in the form of mineral salts) to electrolyte drinks; it was proposed to be deleted and incorporated into the preceding section 2.6.2—9 as a new subsection.

#### **2.3.6.2 Proposed new approach**

It is proposed to remove the reference to ‘mineral’ in relation to the permission to add the mineral salts. In the context of electrolyte drinks, these mineral salts dissociate into functional electrolytes (as charged cations and anions; sodium, potassium, calcium and magnesium and chloride). FSANZ considers that the five aforementioned ‘minerals’ perform the function of an electrolyte when in electrolyte drinks. This means that their labelling should reflect their function as electrolytes rather than as minerals (refer to Section 2.3.7 of this Consultation paper). Note that reference to ‘minerals’ is also proposed to be deleted from the definition of ‘electrolyte drink’.

### **2.3.7 Nutrition information requirements**

#### **2.3.7.1 Approach in 2014 Call for submissions**

The Code generally requires that the labels of packaged food must contain (among other things) nutrition information in accordance with Standard 1.2.8 (see paragraph 1.2.1—8(1)(i)). Standard 1.2.8 requires that packaged food (unless exempted) must include a nutrition information panel (NIP) (section 1.2.8—5). Standard 1.2.8 also contains other requirements relating to NIPs e.g. what information must be included and how to express that information in a NIP (see sections 1.2.8—6 and 1.2.8—7). Additionally, electrolyte drinks are currently required by paragraph 2.6.2—11(1)(a) to include a declaration of the following information on the label of the drink: average energy content; average carbohydrate,

including each type of monosaccharide and disaccharide present; and the milligrams and millimoles of added minerals and electrolytes, per 100 mL of the electrolyte drink as ready to drink.

The draft variation proposed for the 2014 CFS transferred the additional nutrition information requirements for electrolyte drinks from Standard 2.6.2 to Standard 2.9.4 and aligned them with the provisions in Standard 1.2.8 for NIPs. This was to provide consistency in the requirements for the presentation of nutrition information on electrolyte drink labels with other food 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 carbohydrate and energy in Standard 2.6.2 were not retained.

One submitter (industry) specifically noted their support for the proposed amendments. However another industry submitter considered that the proposed amendment would require declarations relating to energy, electrolytes and carbohydrate to be declared in the NIP, including for small packages and stated this is currently not the case.

### **2.3.7.2 Proposed new approach**

The intent for NIPs on electrolyte drinks in 2014 remains the same for the purposes of the example amended draft variation, however the relevant requirements would remain in Standard 2.6.2 rather than moved to Standard 2.9.4. FSANZ considers that the requirements in Standards 1.2.1 and 1.2.8 to label foods with an NIP currently apply to electrolyte drinks and are not new. The proposed approach in 2014 was to remove the duplication and inconsistency between the relevant requirements in Standards 1.2.8 and 2.6.2.

The current requirement in subsection 2.6.2—11(2) to declare the recommended volume and frequency of use on the labels of electrolyte drinks and electrolyte drink bases was inadvertently left out of the draft variation in 2014, however it is proposed that this requirement be retained.

In addition to the requirement in Standard 1.2.8 to declare the average quantity of sodium in the NIP, it is proposed to require the declaration of the average quantity of the other 'prescribed' electrolytes (chloride, calcium, magnesium and potassium) in the NIP when added to electrolyte drinks in the form of a mineral salt listed in Standard 2.6.2, i.e. the total content of each individual electrolyte. The incidental presence of an electrolyte from the use of other ingredients (when not added as an electrolyte from the list of electrolyte salts permitted to be added to electrolyte drinks) does not trigger the requirement for chloride, calcium, magnesium and potassium to be declared in the NIP. The average quantity of sodium however, must always be declared in the NIP, consistent with the requirements currently in Standard 1.2.8 for NIPs.

It is also proposed to exempt electrolyte drinks from the requirement in section 1.2.8—9 to declare the percentage RDI of calcium and magnesium and also to prohibit referring to an RDI in relation to an electrolyte drink. This is intended to reduce consumer confusion about whether or not these are functioning as minerals. Calcium and magnesium are permitted to be added to electrolyte drinks to function as electrolytes, however the requirements for RDIs in the Code are based on their function in the body as minerals. FSANZ therefore considers that percentage RDI declarations are not relevant in the context of electrolyte drinks.

Furthermore, FSANZ proposes that the existing requirement in paragraph 2.6.2—11(1)(a)(iii) to declare added minerals and electrolytes in millimoles is removed. Instead, electrolytes would be required to be declared in milligrams (mg) with additional use of millimoles optional (reference to 'minerals' is removed from the Standard as described in Sections 2.3.4 and 2.3.6 of this Consultation paper). This fits better with the prescribed layout of the NIP, is consistent with the requirement for the declaration of sodium in Standard 1.2.8 and offers some flexibility for industry.

FSANZ also proposes that the requirement in Standard 1.2.8 to declare the average quantity of potassium of the food if a nutrition content or health claim is made about sodium would not

apply. As outlined above, potassium is required to be declared in the NIP if added to the electrolyte drink, and FSANZ considers it could be confusing for consumers in the context of electrolyte drinks if it is declared in the NIP in minimal amounts (if not added as an electrolyte).

For electrolyte drinks that are exempt from the requirement to bear a label (under subsection 1.2.1—6(1), for example, an electrolyte drink poured into a glass in the presence of the purchaser), the existing requirements in Standard 1.2.1 for NIPs would apply. This means that if a nutrition content or health claim is made about the electrolyte drink, the information required for an NIP (see Standards 1.2.8 and 2.6.2) must be displayed in connection with the display of the food or provided to the purchaser upon request (subsections 1.2.1—9(6) and (7)).

Additionally, the current exemption from the requirement to include an NIP on the label of an electrolyte drink or electrolyte drink base in a small package (in Standard 1.2.8) is proposed to continue to apply, and specific conditions for nutrition information on small packages of electrolyte drinks are now proposed. These conditions would apply only if nutrition content or health claims are made about the electrolyte drink and are consistent with the conditions currently applying to small packages in section 1.2.8—14 and Schedule 13, except as they apply to claims about prescribed electrolytes. The conditions in section 1.2.8—14 include a requirement to declare the average quantity of a serving and the quantities of certain claimed nutrients and energy per serving, if a nutrition content or health claim is made. For nutrition content and health claims about electrolytes on electrolyte drinks sold in a small package, the requirements in paragraph 1.2.8—14(1)(b), and therefore Schedule 13, do not apply and specific requirements to declare the average quantity per serving of each electrolyte present (in mg with additional use of millimoles optional) are included in the example amended draft variation. This means that the requirements in Schedule 13 to declare, for example:

- the percentage of the RDI of minerals (calcium and magnesium)
- potassium when a claim about sodium is made
- sodium when a claim about potassium is made,

would not apply when the electrolyte drink or electrolyte drink base is in a small package, consistent with the approach outlined above for NIPs.

## **2.3.8 Claims in relation to the tonicity of electrolyte drinks**

### ***2.3.8.1 Approach in 2014 Call for submissions***

A claim that an electrolyte drink is isotonic can be made if the electrolyte drink has an average osmolality of 250–340 mOsm/L.

The osmolality of any electrolyte drink must currently be declared on the label in mOsm/L if a claim is made that the drink is isotonic, hypertonic or hypotonic (paragraph 1.2.1—8(1)(t) and subsection 2.6.2—12(2)).

No changes were proposed to this approach in 2014.

### ***2.3.8.2 Proposed new approach***

In relation to tonicity claims, FSANZ is not proposing any changes to the current osmolality range defining isotonic claims except for a change to the units (as discussed in Section 2.3.5.2.2 of this Consultation paper above).

The range for isotonic claims can be used to reduce the osmolality range of hypotonic electrolyte drinks as <250 mOsm/kg and hypertonic electrolyte drinks as >340 mOsm/kg.

Despite the proposal to revise the osmolality units for compositional requirements to mOsm/kg, FSANZ considers mOsm/L remains the appropriate unit for declaring osmolality for labelling purposes, as other units of measure on electrolyte drinks are likely to be in litres or millilitres. The difference in tonicity for electrolyte drinks on a kilogram basis compared to a litre basis is no more than about 3% and is expected to be insignificant when rounding is taken into account. This change is likely to have little impact on industry as the new lower bound of the osmolality range for health claims (200 – 340 mOsm/kg) is decreased.

### **2.3.9 Prescribed name**

#### **2.3.9.1 Approach in 2014 Call for submissions**

Standard 1.2.2 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.

In the 2014 CFS, a prescribed name of 'electrolyte drink' was proposed, to help enforcement agencies clearly identify electrolyte drinks. This was supported by the transfer of regulation of electrolyte drinks to Standard 2.9.4 (other foods regulated as Special Purpose Foods have prescribed names) and the removal of the requirement in the definition for electrolyte drinks to be 'represented as'.

There were very few comments about this from submitters however one government submitter supported the proposed approach whereas an industry submitter opposed it. The industry submitter considered there was no demonstrated need for a prescribed name and also considered that the requirement for a prescribed name would warrant WTO notification.

#### **2.3.9.2 Proposed new approach**

FSANZ proposes to maintain the previous proposed approach of prescribing the name 'Electrolyte drink' for electrolyte drinks and electrolyte drink bases.

Although FSANZ is no longer proposing to regulate electrolyte drinks as a special purpose food, there are no provisions in the Code or elsewhere that constrain the use of a prescribed name to special purpose foods. FSANZ still considers it is appropriate to prescribe the name for these products. Electrolyte drink manufacturers are already required to include a name or description to indicate the true nature of the product – the term 'electrolyte drink' is often used. A prescribed name would enable them to be easily identified, in particular for enforcement purposes, to avoid confusion with other similar beverages that do not have the same requirements and permissions, such as FSSF and formulated beverages.

FSANZ's proposed approach regarding WTO notification is in Section 2.5.2 of this Consultation paper.

## **2.4 Related issues**

### **2.4.1 Electrolyte drinks and sugar sweetened beverages**

Section 1.5 of this Consultation paper provides data on the proportion of the population consuming electrolyte drinks compared to other common sugar sweetened beverages. In Australia in 2011–12, 2% of the population (2 years and over) reported consuming electrolyte drinks on one or both of the survey days, compared with 46% of the population consuming other common sugar sweetened beverages. In New Zealand in 2008–9, 1% of the population (15 years and over) reported consuming electrolyte drinks on one or both of the survey days, compared with 54% of the population consuming other common sugar sweetened beverages.

Electrolyte drinks are one type of sugar-sweetened beverage on the market however they are the only category having prescribed minimum and maximum quantity of sugars and a minimum sodium level consistent with their purpose.

Based on declarations in NIPs, Australian sugar-sweetened beverages (including flavoured mineral waters) contain ~ 3–10 g/100 mL total sugars; whereas electrolyte drinks currently contain about 5–6 g/100 mL total sugars. Beverages having lower levels of total sugars may also contain intense sweeteners.

FSANZ now proposes to expand the range of carbohydrate in electrolyte drinks from 50–100 g/L to 20–100 g/L. Many submitters expressed concern about FSANZ's 2014 proposal to permit health claims on electrolyte drink labels but very few acknowledged the existing claim permission for electrolyte drinks that has been in the Code since the early 1990s. Products that appear to be no sugar electrolyte drinks are not regulated as electrolyte drinks, but are instead regulated as formulated beverages that impose a maximum limit on sugars content and also require added vitamins and/or minerals.

FSANZ also proposes a requirement for permitted health claims on electrolyte drinks to explicitly include a minimum time of strenuous physical activity for *60 minutes or more*. This is intended to more precisely describe the appropriate target group for these products and also the non-target group. The beverage industry has identified the target population for electrolyte drinks (and sports drinks) as all active people (gender neutral) 18–49 years old exercising, working out at the gym, competing in sports, or undertaking strenuous physical work.

In 2014, submitters were also concerned about children's unnecessary consumption of electrolyte drinks. FSANZ's dietary exposure assessment (see Section 1.5 above) found electrolyte drink intake among children in both Australia and New Zealand to be relatively low with consumption rates of 2 and 1 percent respectively being reported. The beverage industry has confirmed that electrolyte drinks are not targeted at children and acknowledge electrolyte drinks are not generally suitable for them. Further they recognise the type of physical activity undertaken by children is usually of lower intensity and shorter duration and the use of electrolyte drinks is therefore not necessary. Although the industry notes some competitive young athletes may benefit from the use of electrolyte drinks during prolonged exercise, it believes it is the place of parents/caregivers or coaches to help make this decision.

Further, the label information about the target population in association with health claims would be available to advise parents of the relevance of these products for their children.

As previously mentioned (see Section 1.6 above), Colmar Brunton (2010) noted that electrolyte drinks are also consumed because of their lower carbohydrate levels than other sugar-sweetened beverages. These consumers see electrolyte drinks as an alternative to soft drinks when purchasing for thirst or lethargy related reasons as they view electrolyte drinks to be healthier than soft drinks.

#### **2.4.2 Use of intense sweeteners**

With the proposed reduction in the amount of carbohydrate potentially available to electrolyte drinks, intense sweeteners may be more commonly used to boost the sweetness of electrolyte drinks. Permissions for intense sweeteners for water-based flavoured drinks and electrolyte drinks are listed in item 14.1.3 of the table to section S15—5 and all such permissions have maximum limits. Limitations on the use of intense sweeteners are outlined Standard 1.3.1 (subsection 1.3.1—5), which states a substance that may be used as a food additive to perform the technological purpose of an intense sweetener, may be added to a food only: as a flavour enhancer or in an amount necessary to replace, either wholly or partially, the sweetness normally provided by sugars.

#### **2.4.3 The use of the term 'electrolyte'**

FSANZ is aware of the increasing use of the term *electrolyte* on foods other than electrolyte drinks such as sports waters, formulated beverages, and other products. The more general use of *electrolyte* falls outside the scope of this proposal, but it may be reviewed under P1010.

## **2.5 Risk communication**

### **2.5.1 Consultation**

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

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this proposal. Following the CFS, FSANZ had regard to all submissions made during the submission period, industry representations and recent market developments, which resulted in a change in the direction and scope of the proposal. FSANZ thus determined that additional consultation was required on this change in direction and scope 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 Consultation papers are notified via the FSANZ Notification Circular, media release, through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment via email.

### **2.5.2 World Trade Organization (WTO)**

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members 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 Codex, EU or US commodity standards for electrolyte drinks. Other than scientific opinion guiding health claims on 'carbohydrate electrolyte solutions' in the EU and exercise and fluid replacement in the US, there are currently no other relevant national food standards or regulations pertaining to Electrolyte Drinks (see section 1.4 above). Amending the composition and labelling of electrolyte drinks in the Code 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 Agreement is not considered necessary.

## **2.6 FSANZ Act assessment requirements**

As explained in the 2014 CFS, FSANZ had regard to the matters listed in section 59 of the FSANZ Act when assessing the proposal and then deciding to develop the draft variation that was the subject of that CFS. FSANZ is now required to decide whether to approve, amend or reject the draft variation that it prepared in 2014. The matters listed in sections 18 and 59 of the FSANZ Act remain relevant to that decision. After having regard to these matters, FSANZ's preliminary view is that the draft variation should be amended in the manner described in this paper. See also the example amended draft variation provided at Attachment A.

### **2.6.1 Section 59**

#### **2.6.1.1 Costs and benefits considerations**

Information on the market value and volume of sports drinks is given in Section 1.6 of this Consultation paper.

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the proposal, as amended, 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) had previously exempted FSANZ from the need to undertake a formal Regulation Impact Statement (RIS) in relation to the regulatory

changes proposed in response to the original proposal (ID: 16662). Given the significant change in direction of the proposal, FSANZ sought further advice from the OPBR, who subsequently confirmed they are satisfied that the currently proposed variation is deregulatory and is likely to only have a minor effect on consumers, businesses, and government (ID: 43269).

FSANZ, however, has given consideration to the potential costs and benefits that may arise from the proposed measures in the example amended draft variation for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 59 (2)(a)). The purpose of this consideration is to determine if the community, industry and government as a whole is likely to benefit, on balance, from a change to the status quo. This analysis considers amending the current electrolyte drink regulations in Standard 2.6.2. FSANZ is of the view that no other realistic food regulatory measures exist at this point in time, however information received may result in FSANZ arriving at a different outcome. The classification of electrolyte drinks and the transfer of these provisions within the Code may be further considered under P1010.

The consideration of the costs and benefits in this section of this Consultation paper is not intended to be an exhaustive, quantitative economic analysis of the proposed amendments and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of amending the current electrolyte drink regulations.

**Consumers:** FSANZ considers the revised labelling requirements would provide consumers with better information to facilitate informed decision making together with wider choice (i.e. more healthier options) within the electrolyte drink category. FSANZ also considers the requirement to refer to 60 minutes or more of strenuous physical activity when making a permitted health claim would aid consumers, in both the target and non-target groups, to identify the specific conditions under which electrolyte drink products should be consumed.

**Industry:** The proposed amendment to reduce the prescribed minimum carbohydrate amount from 50 g/L to 20 g/L, consistent with the assessed scientific evidence, would provide the beverage industry with the opportunity to innovate with lower carbohydrate electrolyte drinks within this category. The example amended draft variation is less prescriptive and allows more preapproved health claims about hydration and performance than are currently permitted, and do not require self-substantiation which can be a costly undertaking for industry. It would also identify which substances are electrolytes and regulate electrolyte content claims. A prescribed name would be required. Electrolyte drink manufacturers are already required to include a name or description to indicate the true nature of the product – the term ‘electrolyte drink’ is often used. Therefore, the impact of mandating a prescribed name on electrolyte drinks is considered small relative to the likely benefits of the permissions.

**Government:** There are no additional costs to government. The proposed mandatory prescribed name would assist enforcement agencies to identify electrolyte drink products from other water-based beverages.

### ***Conclusions from cost benefit considerations***

FSANZ’s assessment is that the direct and indirect benefits that would arise from proceeding with the example amended draft variation (if approved) as outlined above, are likely to outweigh the costs to the community, government and industry.

#### ***2.6.1.2 Other measures***

FSANZ is not aware of any other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of this proposal.

### **2.6.1.3 Any relevant New Zealand standards**

The relevant Standards apply in both Australia and New Zealand. There are no relevant New Zealand only standards for electrolyte drinks.

### **2.6.1.4 Any other relevant matters**

Other relevant matters are considered below.

## **2.6.2 Subsection 18(1)**

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

### **2.6.2.1 The protection of public health and safety**

The consumption of electrolyte drinks is only a small proportion of consumption of sugar sweetened beverages. Notwithstanding, the following proposed amendments would protect public health and safety:

- reduction in minimum carbohydrate
- restrictions on nutrition content claims
- the prohibition on health claims, other than three specific claims which must include a reference to 60 minutes or more of strenuous physical activity (which would aid to identify the target/non-target group).

### **2.6.2.2 The provision of adequate information to enable consumers to make informed food choices**

Generic labelling requirements in the Code would continue to apply to electrolyte drinks in addition to the amendments proposed for electrolyte drinks as discussed in Sections 2.3.7 (nutrition information requirements) and 2.3.9 (prescribed name) of this Consultation paper.

FSANZ has proposed a number of new labelling requirements to clarify the intended end user of electrolyte drinks to better assist consumers to make informed choices. These include requiring permitted health claims to refer to *strenuous physical activity* and to a minimum time period of 60 minutes.

### **2.6.2.3 The prevention of misleading or deceptive conduct**

FSANZ considers that provisions in the example amended draft variation, as discussed above in this Consultation paper, would assist in achieving this objective.

## **2.6.3 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**

FSANZ considered the best available scientific evidence (see Section 2.2 of this Consultation paper and SD1) in relation to all measures proposed in the example amended draft variation. These measures include revising the composition and labelling requirements for electrolyte drinks; and revising the requirements and limitations for nutrition content claims and health claims that may be made in relation to electrolyte drinks.

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

There are no Codex, EU or US commodity standards for the regulation of electrolyte drinks.

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

Reducing the minimum carbohydrate compositional requirement and extending the permission for (amended) health claims to electrolyte drinks with the lower carbohydrate

content and including hypotonic electrolyte drinks, in addition to isotonic, will remove potential barriers to internationally traded electrolyte drinks.

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

FSANZ considers that its modified approach would support fair trading by permitting electrolyte drinks to only carry specified claims that are consistent with their intended purpose.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Ministerial policy guideline on Nutrition, Health and Related Claims<sup>9</sup> is relevant to this regulatory measure.

The new proposed provisions would allow certain nutrition content and health claims to be made about electrolyte drinks in accordance with specified conditions in Standards 2.6.2 and 1.2.7. The conditions in Standard 1.2.7 were developed under Proposal P293 with regard to that Policy Guideline. FSANZ also had regard to this policy guideline when considering the specific conditions for nutrition content and health claims proposed to be incorporated into Standard 2.6.2 under this proposal.

## **3 Draft variation**

Attachment A provides an example of how the draft variation prepared in 2014 could be amended to give effect to the modified approach described in this paper – the Example Amended Draft Variation.

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

Attachments C and D provide the draft variation and explanatory statement that FSANZ prepared for and at the call for submissions in 2014.

### **3.1 Transitional arrangements**

If the proposed modified approach were adopted, FSANZ proposes also providing a transitional arrangement where, during a 12 month transition period commencing on the date of gazettal, an electrolyte drink may be sold if an electrolyte drink complies with either the Code as in force prior to the modified approach being implemented; or the Code as amended to give effect to that approach. The intent would be to provide a 12 month transitional arrangement that covers both stock-in-trade at the time of the commencement of the amendments, as well as electrolyte drinks that are packaged, labelled and made available for sale before the end of the transition period.

### **3.2 Implementation and review**

The amendments made as a result of this proposal could be further considered under the FSANZ review of Standard 2.9.4. The variations are scheduled to be gazetted before the completion of the review of that Standard in P1010.

## **4 References**

### **Sections 1.5 and 1.6 of this Consultation paper**

Australian Bureau of Statistics (2014) National Nutrition and Physical Activity Survey, 2011–12, Basic CURF. Australian Government, Canberra. Available at: [http://www.abs.gov.au/AUSSTATS/abs@.nsf/Latestproducts/4324.0.55.002Main%20Feature\\_s652011-12?opendocument&tabname=Summary&prodno=4324.0.55.002&issue=2011-12&num=&view=](http://www.abs.gov.au/AUSSTATS/abs@.nsf/Latestproducts/4324.0.55.002Main%20Feature_s652011-12?opendocument&tabname=Summary&prodno=4324.0.55.002&issue=2011-12&num=&view=)

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University of Otago and Ministry of Health (2011) A Focus on Nutrition: Key findings of the 2008/09 New Zealand Adult Nutrition Survey. Wellington: Ministry of Health. Available at: <https://www.health.govt.nz/publication/focus-nutrition-key-findings-2008-09-nz-adult-nutrition-survey>

## **Appendix**

- 1 EU Health Claims for Electrolyte Drinks

## **Attachments**

- A. Example amended draft variation to the Australia New Zealand Food Standards Code
- B. Explanatory Statement for the example amended draft variation
- C. Draft variation to the Australia New Zealand Food Standards Code at CFS
- D. Draft Explanatory Statement at CFS

## Appendix 1 – EU Health Claims for Electrolyte Drinks

### History of incorporation of EU-authorized health claims into the Code

As part of P293 – Nutrition, health and related claims, food health relationships based on EU-approved health claims were incorporated into the new Standard 1.2.7, but the following two relating to carbohydrate electrolyte solutions were not at that time:

- carbohydrate electrolyte solutions contribute to the maintenance of endurance performance during prolonged endurance exercise
- carbohydrate electrolyte solutions enhance the absorption of water during physical exercise.

These two EU claims were deferred for further consideration during the transition period for Standard 1.2.7 due to concerns about the differences in compositional conditions for the health claims and for electrolyte drinks, and the fact that most electrolyte drinks could not meet the NPSC, which is a requirement for making a health claim regulated by Standard 1.2.7.

### Evidence for EU claims and conditions

EFSA assessed the evidence for the two claims for electrolyte drinks in 2011. The evidence was not assessed by systematic review, rather the EFSA opinion<sup>11</sup> was based on consensus opinions/reports from authoritative bodies. EFSA explained its reasons as follows (1):

“In cases where there is consensus among scientific experts in the field that a claim is substantiated as evidenced by reports from authoritative scientific bodies, EFSA may base its assessment solely on those reports (e.g., claims on the long established physiological functions of vitamins, essential micronutrients, macronutrients, and water).

For example the assessment of the claim on carbohydrate electrolyte solutions related to the ‘maintenance of endurance performance’ was based on a number of such reports, three of which were cited in the opinion – that of the EU Scientific Committee on Food in 2001 (4) and the reports of the American College of Sports Medicine in 2007 and 2009 (5,6). These reports reflect the consensus opinion of experts based on a large body of scientific evidence on the physiological benefits of consuming fluids and carbohydrate during prolonged (endurance) exercise, generally lasting more than one hour.

EFSA’s conclusion that this claim is substantiated is supported by a more recent meta-analysis of 50 randomised controlled trials performed between 1982 and 2011 (7), none of which were among the 54 references submitted to EFSA for this claim.”.

Both EFSA’s opinion and SD1 refer to the relevant population group as active healthy young individuals performing endurance exercise. Also mentioned is the importance of taking fluids during strenuous physical activity to prevent body water loss greater than 2% body weight to ensure performance is not adversely affected. EFSA further indicates that water loss greater than 2% body weight reduces physical performance, especially when it is taking place over long periods or in hot weather.

EFSA’s assessment of two health effects that received its support are as follows:

#### Enhancement of water absorption during exercise

- In EFSA’s view “The evidence provided by consensus opinions/reports from authoritative bodies shows that glucose-electrolyte solutions with an osmolality which is isotonic or slightly hypotonic with respect to plasma (i.e. 200-330 mOsm/kg water) maximise the rate of water uptake, and that the addition of carbohydrates to electrolyte solutions promotes water absorption in the small intestine. Sodium in a concentration between 20-50 mmol/L stimulates carbohydrate and water uptake in the small intestine, and helps to maintain extracellular fluid volume (SCF, 2001).

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<sup>11</sup> <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2211>.

- EFSA concluded “that a cause and effect relationship has been established between the consumption of carbohydrate-electrolyte solutions and enhancement of water absorption during exercise.”.

### Maintenance of endurance performance

- In EFSA’s view “The evidence provided by consensus opinions/reports from authoritative bodies such as the SCF or the American College of Sports Medicine shows that there is good consensus on the role of beverages containing carbohydrates and electrolytes (in particular sodium) in maintaining performance during prolonged endurance exercise, relative to plain water, and that the consumption of beverages containing electrolytes and carbohydrates during exercise can help maintain fluid and electrolyte balance, as well as endurance exercise performance (Rodriguez et al., 2009; Sawka et al., 2007; SCF, 2001).
- EFSA concluded “that a cause and effect relationship has been established between the consumption of carbohydrate-electrolyte solutions and maintenance of endurance performance.”

The resultant EU claims and conditions are shown in Table A1.

**Table A1: Authorised EU health claims for carbohydrate electrolyte solutions<sup>12</sup>**

Claim	Conditions for use
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 200-330 mOsm/kg water.
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.

Note that FSANZ is not considering another more recent and as yet unauthorised EU claim for carbohydrate solutions<sup>13</sup>.

### EFSA’s references

- 1) Kleiner, J. Rapid response to: *How valid is the European Food Safety Authority’s assessment of sports drink?* BMJ 2012;345:e4753

<sup>12</sup> COMMISSION REGULATION (EU) No 432/2012, 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children’s development and health. Annex, List of Permitted Health Claims

<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32012R0432&from=EN#d1e32-4-1>

<sup>13</sup> the consumption of carbohydrate solutions and the improvement of physical performance during high-intensity and long-lasting physical exercise for the target population of healthy trained adults performing high-intensity (at least at 65% of the VO2max) and long-lasting (at least 60 min) physical exercise. [http://www.puntofocal.gov.ar/notific\\_otros\\_miembros/eu723\\_t.pdf](http://www.puntofocal.gov.ar/notific_otros_miembros/eu723_t.pdf)

4) SCF (Scientific Committee on Food), 2001. Report on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen. SCF/CS/NUT/SPORT/5.

5) Sawka MN, Burke LM, Eichner ER, Maughan RJ, Montain SJ and Stachenfeld NS, 2007. American College of Sports Medicine position stand. Exercise and fluid replacement. *Medicine and Science in Sports and Exercise*, 39, 377-390.

6) Rodriguez NR, Di Marco NM and Langley S, 2009. American College of Sports Medicine position stand. Nutrition and athletic performance. *Medicine and Science in Sports and Exercise*, 41, 709-731.

7) Temesi J, Johnson NA, Raymond J, Burdon CA, O'Connor HT, 2011. Carbohydrate ingestion during endurance exercise improves performance in adults. *Journal of Nutrition*, 141, 890-7.

## Attachment A – Example Amended Draft variation to the Australia New Zealand Food Standards Code



### Food Standards (Proposal P1030 – Composition and Labelling of Electrolyte Drinks) Variation

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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 variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[To be signed by Delegate]

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 – Composition and Labelling of Electrolyte Drinks) Variation*.

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

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

## 3 Commencement

The variation commences on the date of gazettal.

## 4 Effect of the variations made by this instrument

- (1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.
- (2) During the transition period, a food product may be sold if the food product complies with one of the following:
  - (a) the Code as in force without the variations made by this instrument; or
  - (b) the Code as amended by the variations made by this instrument.
- (3) For the purposes of this clause, **transition period** means the period commencing on the variation's date of commencement and ending 12 months after the date of commencement.

### Schedule

[1] **Standard 1.1.2** is varied by omitting the definition of 'electrolyte drink' in subsection 1.1.2—3(2), substituting

**electrolyte drink** means a drink formulated for the rapid replacement of fluid and electrolytes during or after 60 minutes or more of strenuous physical activity.

[2] **Standard 1.2.1** is varied by omitting paragraph 1.2.1—8(1)(t), substituting

- (t) the declarations and other information required for electrolyte drinks and for electrolyte drink bases (see Standard 2.6.2);

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

[3.1] inserting after Note 2 to the Standard

## Division 1 Preliminary

[3.2] omitting section 2.6.2—2, substituting

### 2.6.2—2 Definitions

**Note 1** In this Code (see section 1.1.2—2):

**average quantity**, of a substance in a food, means the average, for such foods from that producer or manufacturer, of:

- (a) where a serving or reference amount is specified—the amount of the substance that such a serving or reference amount contains; or
- (b) otherwise—the proportion of that substance in the food, expressed as a percentage.

**Note** See also section 1.1.1—6.

**claim** means an express or implied statement, representation, design or information in relation to a food or a property of food which is not mandatory in this Code.

**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.

**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.

**Note** See also subsection 2.10.2—8(3).

**nutrition content claim**—see section 1.1.2—9.

**package:**

- (a) means any container or wrapper in or by which food for sale is wholly or partly encased, covered, enclosed, contained or packaged; and
- (b) if food is carried or sold or intended to be carried and sold in more than one package—includes each package; and
- (c) does not include:
  - (i) a \*bulk cargo container; or
  - (ii) a pallet overwrap; or
  - (iii) a crate and packages which do not obscure labels on the food; or
  - (iv) a transportation vehicle; or
  - (v) a vending machine; or
  - (vi) a hamper; or
  - (vii) a container or wrapper (including a covered plate, cup, tray or other food container) in which food is served in a prison, hospital or \*medical institution; or
  - (viii) for Standard 2.9.5—a covered plate, cup, tray or other food container in which food for special medical purposes is served by a \*responsible institution to a patient or resident.

**prescribed name**, of a particular food, means a name declared by a provision of this Code to be the prescribed name of the food.

**Note** Under the labelling provisions in Standard 1.2.1 and section 1.2.2—2, if a food has a prescribed name, it must be used in the labelling of the food.

**property of food** means a \*component, ingredient, constituent or other feature of food.

**small package** means a package with a surface area of less than 100 cm<sup>2</sup>.

**sugars:**

- (a) in Standard 1.2.7, Standard 1.2.8 and Schedule 4 (except where it appears with an asterisk as \*sugars\*)—means monosaccharides and disaccharides; and
- (b) otherwise—means any of the following products, derived from any source:
  - (i) hexose monosaccharides and disaccharides, including dextrose, fructose, sucrose and lactose;
  - (ii) starch hydrolysate;
  - (iii) glucose syrups, maltodextrin and similar products;
  - (iv) products derived at a sugar refinery, including brown sugar and molasses;
  - (v) icing sugar;
  - (vi) invert sugar;
  - (vii) fruit sugar syrup;

but does not include:

- (i) malt or malt extracts; or
- (ii) sorbitol, mannitol, glycerol, xylitol, polydextrose, isomalt, maltitol, maltitol syrup, erythritol or lactitol.

**Note** Sugar is defined differently—see section 1.1.2—3.

**unit quantity** means:

- (a) for a food that is a solid or semi-solid food—100 grams; or
- (b) for a food that is a beverage or other liquid food—100 millilitres.

**Note 2** In this Code (see section 1.1.2—3):

**brewed soft drink** means a food that:

- (a) is the product prepared by a fermentation process from water with sugar and one or more of:
  - (i) fruit extractives or infusions; or
  - (ii) vegetable extractives or infusions; and
- (b) contains no more than 1.15% alcohol by volume.

**electrolyte drink** means a drink formulated for the rapid replacement of fluid and electrolytes during or after 60 minutes or more of strenuous physical activity.

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

**formulated beverage** means a non-carbonated, ready-to-drink, flavoured beverage that:

- (a) is water-based; and
- (b) contains added vitamins or minerals or both vitamins and minerals; and
- (c) contains no more than 240 mL/L of fruit from one or more of the following sources:
  - (i) fruit juice;

- (ii) fruit purée;
- (iii) concentrated fruit juice;
- (iv) concentrated fruit purée;
- (v) comminuted fruit;
- (vi) orange peel extract; and
- (d) contains no more than 75 g/L of sugars; and
- (e) does not contain:
  - (i) carbon dioxide; or
  - (ii) caffeine; and
- (f) is not mixed with any other beverage.

**fruit drink** means a product that is prepared from:

- (a) one or more of the following:
  - (i) fruit juice;
  - (ii) fruit purée;
  - (iii) concentrated fruit juice;
  - (iv) concentrated fruit purée;
  - (v) comminuted fruit;
  - (vi) orange peel extract; and
- (b) one or more of the following:
  - (i) water;
  - (ii) mineralised water; and
  - (iii) sugars.

**mineral water** or **spring water** means ground water obtained from subterranean water-bearing strata that, in its natural state, contains soluble matter.

**non-alcoholic beverage:**

- (a) means:
  - (i) packaged water; or
  - (ii) a water-based beverage, or a water-based beverage that contains other foods (other than alcoholic beverages); or
  - (iii) an electrolyte drink; and
- (b) does not include a brewed soft drink.

**sugar** means, unless otherwise expressly stated, any of the following:

- (a) white sugar;
- (b) caster sugar;
- (c) icing sugar;
- (d) loaf sugar;
- (e) coffee sugar;
- (f) raw sugar.

**Note 3** In this Code (see subsection 1.1.2—9(1))

**nutrition content claim** means a claim that:

- (a) is about:
  - (i) the presence or absence of any of the following:
    - (A) \*biologically active substance;
    - (B) \*dietary fibre;
    - (C) energy;
    - (D) minerals;
    - (E) potassium;
    - (F) protein;
    - (G) \*carbohydrate;
    - (H) 'fat',
    - (I) the components of any one of protein, carbohydrate or 'fat',
    - (J) \*salt;
    - (K) sodium;
    - (L) vitamins; or
  - (ii) \*glycaemic index or glycaemic load; and
- (b) does not refer to the presence or absence of alcohol; and
- (c) is not a \*health claim.

**Note** See also subsections 2.6.2—5(4) and 2.10.2—8(3).

## **Division 2 Packaged water**

[3.3] inserting after section 2.6.2—5

## **Division 3 Non-alcoholic beverages and brewed soft drinks**

[3.4] omitting sections 2.6.2—9 to 2.6.2—13 inclusive, substituting

### **2.6.2—9 Requirement for food sold as a formulated beverage**

A food sold as a formulated beverage must be a formulated beverage.

## **Division 4 Electrolyte drinks and electrolyte drink bases**

### **2.6.2—10 Definitions and interpretation**

#### *Definitions*

(1) In this Division:

**Prescribed electrolyte** means any of the following:

- (a) sodium;
- (b) potassium;
- (c) calcium;
- (d) magnesium;
- (e) chloride.

#### *Interpretation of compositional and declaration requirements*

(2) For an electrolyte drink base, the compositional and declaration requirements in this Division apply to an electrolyte drink base as ready to drink.

### **2.6.2—11 Composition of electrolyte drink or electrolyte drink base**

(1) A food that is sold as an electrolyte drink or an electrolyte drink base must be an electrolyte drink or an electrolyte drink base, as appropriate.

(2) An electrolyte drink or electrolyte drink base must contain:

- (a) no less than 10 mmol/L of sodium; and
- (b) no less than 20 g/L and no more than 100 g/L in total of the following:
  - (i) dextrose;
  - (ii) fructose;
  - (iii) glucose syrup;
  - (iv) maltodextrin;
  - (v) sucrose; and
- (c) no more than 20 g/L fructose.

(3) An electrolyte drink or electrolyte drink base may contain:

- (a) calcium phosphates;
- (b) potassium phosphates;
- (c) calcium citrates;
- (d) potassium citrates;
- (e) sodium citrates;
- (f) potassium carbonates, including potassium bicarbonate;
- (g) potassium chloride;

- (h) calcium chloride;
- (i) sodium chloride;
- (j) calcium lactate;
- (k) magnesium lactate;
- (l) magnesium sulphate.

### 2.6.2—12 Labelling of electrolyte drinks and electrolyte drink bases

- (1) 'Electrolyte drink' is a \*prescribed name for an electrolyte drink and an electrolyte drink base.
- (2) For the labelling provisions, the following information is required:
  - (a) the recommended volume and frequency of use; and
  - (b) the nutrition information panel must also declare the \*average quantity per serving and per \*unit quantity of:
    - (i) each type of monosaccharide present; and
    - (ii) each type of disaccharide present; and
    - (iii) subject to subsection (3), each prescribed electrolyte present (other than sodium), expressed in milligrams or both milligrams and millimoles.

**Note 1:** The labelling provisions are set out in Standard 1.2.1.

**Note 2:** Section 1.2.8—5 provides that packaged food (unless exempted) must include a nutrition information panel (NIP). Standard 1.2.8 also contains other requirements relating to NIPs e.g. what information must be included and how to express that information in a NIP (see sections 1.2.8—6 and 1.2.8—7). The requirements set out in paragraph 2.6.2—12(2)(b) are in addition to those other requirements.

**Note 3:** Subparagraph 1.2.8—6(1)(d)(iii) requires that a nutrition information panel must contain (among other information) the average quantity of sodium, expressed in milligrams or both milligrams and millimoles for a serving of the food and a unit quantity of the food.

- (3) Subparagraph 2.6.2—12(2)(b)(iii) applies only in relation to an electrolyte drink or an electrolyte drink base to which a substance listed in subsection 2.6.2—11(3) has been added.

### 2.6.2—13 Labelling requirement for electrolyte drinks and electrolyte drink bases in small packages

- (1) This section applies to an electrolyte drink or electrolyte drink base:
  - (a) that is in a \*small package; and
  - (b) about which a \*claim requiring nutrition information is made; and
  - (c) the claim relates to a prescribed electrolyte.
- (2) For the labelling provisions, the required information includes the \*average quantity per serving of each prescribed electrolyte present, expressed in milligrams or both milligrams and millimoles.

**Note 1:** The labelling provisions are set out in Standard 1.2.1.

**Note 2:** The requirements of this subsection are in addition to the requirements set out in section 1.2.8—14. Section 1.2.8—14 sets out requirements for food for sale in a small package where a claim requiring nutrition information is made in relation to the food.

- (3) Paragraph 1.2.8—14(1)(b) does not apply to a \*claim requiring nutrition information that is made about a prescribed electrolyte.

**Note:** Paragraph 1.2.8—14(1)(b) sets out nutrition information requirements for food for sale in a small package where a claim requiring nutrition information is made about a matter listed in Column 1 of the table to section S13—2 (such as sodium or a mineral with a Recommended Dietary Intake (RDI)).

### 2.6.2—14 Recommended dietary intake information prohibited

- (1) An \*RDI must not be stated or declared in relation to an electrolyte drink or electrolyte drink base.

- (2) Section 1.2.8—9 does not apply to an electrolyte drink or electrolyte drink base.

**Note:** Section 1.2.8—9 relates to minerals with an RDI (among other things). Some of the substances listed as 'prescribed electrolytes' in section 2.6.2—10 are also minerals with an RDI for the purposes of section 1.2.8—9 e.g. calcium and magnesium (see also the table to section S1—3).

## **2.6.2—15 Nutrition content claims about electrolyte drinks and electrolyte drink bases**

- (1) A nutrition content claim must not be made about an electrolyte drink or electrolyte drink base unless:
- (a) subject to paragraph (2)(b), the claim is made in accordance with Division 4 of Standard 1.2.7; and
  - (b) the claim is about any of the following:
    - (i) sugar or sugars; or
    - (ii) carbohydrate; or
    - (iii) energy; or
    - (iv) the presence of one or more prescribed electrolytes.
- (2) If a nutrition content claim is made under subparagraph (1)(b)(iv):
- (a) the claim must only state that the electrolyte drink or electrolyte drink base contains one or both of the following:
    - (i) electrolytes;  
**Example:** Contains electrolytes.
    - (ii) a prescribed electrolyte that is present in the food, provided that the claim also states that the prescribed electrolyte is an electrolyte; and  
**Example:** This food contains the electrolytes: calcium and sodium.
  - (b) any conditions for nutrition content claims in Standard 1.2.7 that relate to a prescribed electrolyte present in the food do not apply to the nutrition content claim.

## **2.6.2—16 Health claims about electrolyte drinks and electrolyte drink bases**

- (1) Standard 1.2.7 does not apply to a \*health claim made about an electrolyte drink or electrolyte drink base.
- (2) A \*health claim must not be made about an electrolyte drink or electrolyte drink base unless:
- (a) the food has an average osmolality of 200–340 mOsmol/kg; and
  - (b) the claim is about any of the following:
    - (i) rapid rehydration in association with words to the effect of 'after at least 60 minutes or more of strenuous physical activity';
    - (ii) rapid hydration in association with words to the effect of 'during at least 60 minutes or more of strenuous physical activity';
    - (iii) contribution to the maintenance of performance by rapid hydration in association with words to the effect of 'during at least 60 minutes or more of strenuous physical activity'.
- (3) In a \*health claim made under subsection (2), the amount of time must be expressed only as a quantifiable amount of time.  
**Examples:** '60 minutes' or 'sixty minutes'; '1 hour' or 'one hour'.
- (4) Subject to subsection (3), nothing in this section is to be taken to prescribe the words that must be used when making a \*health claim under this section.  
**Example:** 'exercise' instead of 'physical activity'.

## **2.6.2—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 mOsm/kg.

- (2) For the labelling provisions, for an electrolyte drink about which a claim is made that the drink is isotonic, hypertonic or hypotonic, the following information is required—a declaration of the osmolality of the electrolyte drink, expressed in mOsm/L.

**Note:** The labelling provisions are set out in Standard 1.2.1.

## 2.6.2—18

### **Claims in relation to sodium in electrolyte drinks and electrolyte drink bases**

Subsection 1.2.8—6(12) does not apply to a \*claim requiring nutrition information that is made in relation to salt or sodium in an electrolyte drink or electrolyte drink base.

**Note:** Subsection 1.2.8—6(12) provides that, if a claim requiring nutrition information is made in relation to salt or sodium in a food product, the nutrition information panel for that product must include a declaration of the average quantity of potassium in accordance with section S12—3.

## **Attachment B – Draft Explanatory Statement (example only)**

### **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.

The Authority had prepared Proposal P1030 to permit formulated supplementary sports foods, electrolyte drinks and 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 had considered the Proposal in accordance with Division 2 of Part 3 of the FSANZ Act and prepared a draft variation.

The Authority called for submissions on that draft variation in 2014 under section 61 of the FSANZ Act and has had regard to all submissions made during the call for submissions in accordance with subsection 63(2) of the Act. Consequently, the Authority has further considered the Proposal in accordance with Division 2 of Part 3 of the FSANZ Act; and revised the scope and direction of the Proposal to limit its focus on the composition and labelling of electrolyte drinks. The regulation of electrolyte drinks and electrolyte drink bases will remain in Part 2.6 of the Code and not be transferred to Part 2.9 as previously proposed.

The Authority has amended the draft variation accordingly.

### **2. Purpose**

The Authority has prepared an amended draft variation that amends Standards 1.1.2, 1.2.1 and 2.6.2 of the Code to improve the regulation of the composition and labelling of electrolyte drinks and electrolyte drink bases. This includes amending the definition of 'electrolyte drink'; reducing the minimum level of carbohydrate; and setting out revised requirements and limitations for nutrition content claims and health claims that may be made in relation to electrolyte drinks and electrolyte drink bases.

### **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 has to date included one round of public consultation in 2014 following an assessment and the preparation of a draft variation and associated report.

As stated above, the Authority has amended the scope of Proposal P1030 following the call for submissions in 2014 and prepared an amended draft variation. The Authority is now consulting with stakeholders on the amended draft variation.

The Office of Best Practice Regulation (OBPR) had previously exempted FSANZ from the

need to undertake a formal Regulation Impact Statement (RIS) in relation to the regulatory changes proposed in response to this Proposal (ID: 16662). The Proposal has undergone significant change in direction since the CFS, so FSANZ sought further advice from the OPBR, who subsequently confirmed they are satisfied that the sought variation is deregulatory and is likely to only have a minor effect on consumers, businesses, and government (ID: 43269).

## 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 1.1.2 – Definitions used throughout the Code***

**Item [1]** amends the definition of ‘electrolyte drink’ in subsection 1.1.2—3(2). The new definition is:

‘**electrolyte drink** means a drink formulated for the rapid replacement of fluid and electrolytes during or after 60 minutes or more of strenuous physical activity.’

### ***Standard 1.2.1 – Requirements to have labels or otherwise provide information***

**Item [2]** amends Standard 1.2.1. The item amends the reference in paragraph 1.2.1—8(1)(t) to information requirements in Standard 2.6.2 for electrolyte drinks and electrolyte drink bases as a consequence of amendments made to Standard 2.6.2 (see **item [3]** below), including the numbering of relevant provisions in that Standard.

### ***Standard 2.6.2 – Non-alcoholic beverages and brewed soft drinks***

**Item [3]** amends Standard 2.6.2 as follows.

**Subitem [3.1]** inserts the heading of the first of four new Divisions in Standard 2.6.2 after *Note 2* to that Standard: ‘**Division 1 Preliminary**’. Division 1 encompasses sections 2.6.2—1 and 2.6.2—2.

**Subitem [3.2]** replaces section 2.6.2—2 with a new section containing three new Notes, each of which sets out the definitions of certain terms from sections 1.1.2—2, 1.1.2—3 and 1.1.2—9 respectively.

This subitem also inserts the following Division heading after section 2.6.2—2: ‘**Division 2 Packaged water**’. Division 2 encompasses sections 2.6.2—3 to 2.6.2—5 inclusive.

**Subitem [3.3]** inserts the following Division heading after section 2.6.2—5: ‘**Division 3 Non-alcoholic beverages and brewed soft drinks**’. Division 3 encompasses sections 2.6.2—6 to 2.6.2—9 inclusive.

**Subitem [3.4]** replaces sections 2.6.2—9 to 2.6.2—13 inclusive, with new provisions sections 2.6.2—9 to 2.6.2—18.

*Section 2.6.2—9* requires that a food sold as a formulated beverage must be a formulated beverage. This is the same requirement as currently set out in section 2.6.2—13. As a formulated beverage is a non-alcoholic beverage, section 2.6.2—13 was moved up in the

Standard (and renumbered accordingly) to be located with other provisions relating to non-alcoholic beverages and brewed soft drinks in Division 3 of the Standard.

This subitem also inserts the following Division heading after section 2.6.2—9: '**Division 4 Electrolyte drinks and electrolyte drink bases**'. Division 4 encompasses sections 2.6.2—10 to 2.6.2—18 inclusive.

*Section 2.6.2—10* contains the following preliminary provisions applying to electrolyte drinks and electrolyte drink bases.

Subsection 2.6.2—10(1) sets out the definition of 'prescribed electrolyte' for the purposes of Division 4. 'Prescribed electrolyte' means any of the following:

- sodium;
- potassium;
- calcium;
- magnesium;
- chloride.

This definition has been provided because some of the substances listed as 'prescribed electrolytes' for the purposes of Division 4 are also 'minerals' for the purposes of requirements elsewhere in the Code.

Subsection 2.6.2—10(2) clarifies that for an electrolyte drink base, the compositional and declaration requirements in this Division apply to the electrolyte drink base as ready to drink.

*Section 2.6.2—11* sets out the following compositional requirements for electrolyte drinks and electrolyte drink bases.

Subsection 2.6.2—11(1) requires that a food sold as an electrolyte drink or an electrolyte drink base must be an electrolyte drink or an electrolyte drink base respectively.

Subsection 2.6.2—11(2) requires that an electrolyte drink or electrolyte drink base must contain:

- no less than 10 mmol/L of sodium; and
- no less than 20 g/L and no more than 100 g/L in total of the following:
  - dextrose;
  - fructose;
  - glucose syrup;
  - maltodextrin;
  - sucrose; and
- no more than 20 g/L fructose.

Subsection 2.6.2—11(3) allows an electrolyte drink or electrolyte drink base to contain:

- calcium phosphates;
- potassium phosphates;
- calcium citrates;
- potassium citrates;
- sodium citrates;
- potassium carbonates, including potassium bicarbonate;
- potassium chloride;
- calcium chloride;
- sodium chloride;

- calcium lactate;
- magnesium lactate;
- magnesium sulphate.

Section 2.6.2—12 sets out the following labelling requirements for electrolyte drinks and electrolyte drink bases.

Subsection 2.6.2—12(1) provides that ‘Electrolyte drink’ is a prescribed name for an electrolyte drink and an electrolyte drink base.

The ‘prescribed name’ of a food is a term defined in subsection 1.2.1—2(3) [see subitem 3.2 of the amended draft variation]. The labelling provisions in Standard 1.2.1 and section 1.2.2—2 provide that, if a food has a prescribed name, that name must be used in the labelling of the food.

Subsection 2.6.2—12(2) requires the following information to be provided for the labelling provisions:

- the recommended volume and frequency of use (paragraph 2.6.2—12(2)(a)); and
- the nutrition information panel must also declare the average quantity per serving and per unit quantity of the following (2.6.2—12(2)(b)):
  - each type of monosaccharide present; and
  - each type of disaccharide present; and
  - subject to subsection 2.6.2—12(3) (see below), each prescribed electrolyte present (other than sodium), expressed in milligrams or both milligrams and millimoles.

‘Average quantity’ and ‘unit quantity’ are terms defined in subsection 1.1.2—2(3) [see subitem 3.2 of the amended draft variation].

*Note 1* to subsection 2.6.2—12(2) explains that labelling provisions are contained in Standard 1.2.1.

*Note 2* to subsection 2.6.2—12(2) explains that according to section 1.2.8—5, packaged food (unless exempted) must include a nutrition information panel (NIP). This means that packaged electrolyte drinks and electrolyte drink bases must have an NIP unless an exemption applies, for example, the electrolyte drink or electrolyte drink base concerned is in a small package.

*Note 2* also explains that Standard 1.2.8 also contains other requirements relating to NIPs, for example, information that must be included and how to express that information (see sections 1.2.8—6 and 1.2.8—7). The requirements set out in paragraph 2.6.2—12(2)(b) are in addition to those other requirements.

*Note 3* explains that subparagraph 1.2.8—6(1)(d)(iii) already requires that a nutrition information panel must contain (among other information) the average quantity of sodium, expressed in milligrams or both milligrams and millimoles for a serving of the food and a unit quantity of the food.

Subsection 2.6.2—12(3) provides that the requirement in subparagraph 2.6.2—2(2)(b)(iii) applies only in relation to an electrolyte drink or an electrolyte drink base to which a substance listed in subsection 2.6.2—11(3) has been added.

The effect of both paragraph 2.6.2—12(2)(b) and subsection 2.6.2—12(3) is that *where a substance listed in subsection 2.6.2—11(3) has been added to an electrolyte drink or*

*electrolyte drink base*, the average quantity per serving and per unit quantity of each prescribed electrolyte that is present in the electrolyte drink or electrolyte drink base must be declared. These quantities are based on the *total amount* of a prescribed electrolyte that is present in the electrolyte drink or electrolyte drink base, i.e. the amount of the prescribed electrolyte derived from *all* sources added to the electrolyte drink or electrolyte drink base—derived from a substance listed in 2.6.2—11(3); and from any other substance such as an intense sweetener.

Section 2.6.2—13 sets out the following labelling requirements for electrolyte drinks and electrolyte drink bases in small packages.

Subsection 2.6.2—13(1) clarifies that requirements in this section apply to an electrolyte drink or electrolyte drink base:

- that is in a small package; and
- about which a claim requiring nutrition information is made; and
- the claim relates to a prescribed electrolyte.

The terms ‘a small package’ and ‘a claim requiring nutrition information’ are defined in subsection 1.1.2—2(3) [see subitem 3.2 of the amended draft variation].

Subsection 2.6.2—13(2) provides that for the labelling provisions, the required information includes the average quantity per serving of each prescribed electrolyte present, expressed in milligrams or both milligrams and millimoles.

*Note 1* to this subsection explains that labelling provisions are contained in Standard 1.2.1.

*Note 2* to this subsection explains that the requirements of subsection 2.6.2—13(2) are in addition to the requirements set out in section 1.2.8—14. Section 1.2.8—14 sets out requirements for food for sale in a small package where a claim requiring nutrition information is made in relation to the food.

Subsection 2.6.2—13(3) provides that paragraph 1.2.8—14(1)(b) does not apply to an electrolyte drink or electrolyte drink base in a small package when making a claim requiring nutrition information relating to a *prescribed electrolyte*.

The *Note* to this subsection explains that paragraph 1.2.8—14(1)(b) sets out nutrition information requirements for food for sale in a small package where a claim requiring nutrition information is made about a matter listed in Column 1 of the table to section S13—2 (such as sodium or a mineral with a Recommended dietary intake (RDI)).

Section 2.6.2—14 contains the following prohibitions related to RDI information for electrolyte drinks and electrolyte drink bases.

Subsection 2.6.2—14(1) provides that an RDI must not be stated or declared in relation to an electrolyte drink or electrolyte drink base.

Subsection 2.6.2—14(2) provides that section 1.2.8—9 does not apply to an electrolyte drink or electrolyte drink base.

A *Note* to this subsection explains that section 1.2.8—9 relates to percentage RDI information and applies to minerals with an RDI (among other things). As stated above, some of the substances listed as ‘prescribed electrolytes’ in subsection 2.6.2—10(1) are also minerals with an RDI for the purposes of section 1.2.8—9, for example, calcium and magnesium (see also the table to section S1—3).

Section 2.6.2—15 contains the following requirements and limitations for making nutrition content claims about electrolyte drinks and electrolyte drink bases.

'Nutrition content claim' is defined in section 1.1.2—9 [see subitem 3.2 of the amended draft variation].

Subsection 2.6.2—15(1) only allows a nutrition content claim to be made about an electrolyte drink or electrolyte drink base if both of the following conditions are satisfied:

- subject to paragraph 2.6.2—15(2)(b), the claim is made in accordance with Division 4 of Standard 1.2.7 (*Requirements for nutrition content claims*); and
- the claim is about any of the following:
  - sugar or sugars content; or
  - carbohydrate content; or
  - energy; or
  - the presence of one or more prescribed electrolytes.

'Sugars' is defined in subsection 1.1.2—2(3) [see subitem 3.2 of the amended draft variation].

Subsection 2.6.2—15(2) provides that if a nutrition content claim made under subsection 2.6.2—15(1) is about the presence of one or more prescribed electrolytes:

- the claim must only state that the electrolyte drink or electrolyte drink base contains one or both of the following:
  - electrolytes (for example, 'Contains electrolytes');
  - a prescribed electrolyte is present in the food, provided that the claim also states that the prescribed electrolyte is an electrolyte (for example, 'This food contains the electrolytes: calcium and sodium'); and
- any conditions for nutrition content claims in Standard 1.2.7 relating to a prescribed electrolyte present in the food do not apply to the nutrition content claim (this is because, as stated above, some substances listed as 'prescribed electrolytes' in subsection 2.6.2—10(1) are also 'minerals' for the purposes of requirements elsewhere in the Code, for example, Standard 1.2.7).

Section 2.6.2—16 contains the following requirements and limitations for health claims about electrolyte drinks and electrolyte drink bases.

Subsection 2.6.2—16(1) provides that Standard 1.2.7 does not apply to a health claim made about an electrolyte drink or electrolyte drink base.

'Health claim' is defined in subsection 1.1.2—2(3) [see subitem 3.2 of the amended draft variation].

Subsection 2.6.2—16(2) only allows health claims to be made if both of the following conditions are satisfied:

- the food has an average osmolality of 200–340 mOsmol/kg; and
- the claim is about any of the following:
  - rapid rehydration in association with words to the effect of 'after at least 60 minutes or more of strenuous physical activity';
  - rapid hydration in association with words to the effect of 'during at least 60 minutes or more of strenuous physical activity';

- contribution to the maintenance of performance by rapid hydration in association with words to the effect of ‘during at least 60 minutes or more of strenuous physical activity’.

Subsection 2.6.2—16(3) requires that where a health claim is made under subsection 2.6.2—16(2), the amount of time must be expressed only as a quantifiable amount of time. For example, ‘60 minutes’ or ‘sixty minutes’; ‘1 hour’ or ‘one hour’.

Subsection 2.6.2—16(4) clarifies that, *subject to subsection 2.6.2—16(3)*, nothing in section 2.6.2—16 is to be taken to prescribe the words that must be used when making a health claim under this section. For example, one may state ‘exercise’ instead of ‘physical activity’.

*Section 2.6.2—17* contains the following requirements for making a claim in relation to the tonicity of an electrolyte drink.

‘Claim’ is defined in subsection 1.1.2—2(3) [see subitem 3.2 of the amended draft variation].

Subsection 2.6.2—17(1) only allows a claim to be made that an electrolyte drink is isotonic if the electrolyte drink has an average osmolality of 250–340 mOsmol/kg.

Subsection 2.6.2—17(2) requires that a declaration of the osmolality of the electrolyte drink, (expressed in mOsm/L) be made for the labelling provisions if a claim is made that an electrolyte drink is isotonic, hypertonic or hypotonic.

A *Note* to the subsection explains that the labelling provisions are set out in Standard 1.2.1.

*Section 2.6.2—18* states that subsection 1.2.8—6(12) does not apply to a claim requiring nutrition information that is made in relation to salt or sodium in an electrolyte drink or electrolyte drink base.

A *Note* to the section explains that subsection 1.2.8—6(12) provides that, if a claim requiring nutrition information is made in relation to salt or sodium in a food product, the nutrition information panel for that product must include a declaration of the average quantity of potassium in accordance with section S12—3.

### ***Transitional arrangements***

The above variations will commence or take effect on the date of gazettal. See clause 3 of the instrument of variation.

The stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 will not apply to any of the above variations. See clause 4 of the instrument of variation.

Clause 4 provides a transitional arrangement where, during a 12 month transition period commencing on the date of gazettal, an electrolyte drink or electrolyte drink base may be sold if an electrolyte drink or electrolyte drink base complies with either the Code as in force without the amendments made by the amended draft variation; or the Code as amended by the amended draft variation. The intent is to provide a 12 month transitional arrangement that covers both stock-in-trade at the time of the commencement of the variations, as well as electrolyte drinks or electrolyte drink bases that are packaged, labelled and made available for sale before the end of the transition period.

## Attachment C – Draft variation to the Australia New Zealand Food Standards Code at call for submissions



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

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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	Diocetyl 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 D – Draft Explanatory Statement at call for submissions**

### **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.