

**22 June 2022**  
**206 -22**

## Approval Report – Proposal P1030

### Composition and Labelling of Electrolyte Drinks

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Food Standards Australia New Zealand (FSANZ) has assessed a Proposal to review the regulation of electrolyte drinks in the *Australia New Zealand Food Standards Code*.

On 18 August 2014, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 39 submissions. On 28 May 2021, FSANZ sought additional stakeholder input on an amended draft variation and published an associated report. FSANZ received 17 submissions.

FSANZ approved an amended draft variation on 8 June 2022. The Food Ministers' Meeting was notified of FSANZ's decision on 22 June 2022.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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## Supporting document

The [following documents](#) which informed the assessment of this Proposal are available on the FSANZ website:

SD1 Risk Assessment (at Approval)

SD2 Electrolyte drink market, consumption and consumer research (at Approval)

## Executive summary

Proposal P1030 was prepared to assess whether formulated supplementary sports foods (FSSF), electrolyte drinks and electrolyte drink bases<sup>1</sup> should be permitted to carry health claims consistent with their intended purpose related to strenuous physical activity. The other objective of this Proposal was to transfer 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 prepared a draft variation to the Code that would give effect to the above. A Call for Submissions was issued in 2014. Submitters generally did not support the proposed changes to the Code.

After considering stakeholder submissions, and after taking into account recent market developments, FSANZ in May 2021 sought stakeholder views on a possible modified approach. FSANZ released a Consultation Paper seeking views on an amended draft variation, and received 17 submissions in response.

After consideration of all submissions received in 2014 and in 2021, and for the reasons set out in this Report, FSANZ has approved an amended final draft variation. The approved draft variation will:

- Amend the definition of ‘electrolyte drink’ to align more closely with compositional requirements and ensure product differentiation.
- Prescribe the name ‘electrolyte drink’ to enable improved identification of electrolyte drinks among similar products not regulated as electrolyte drinks.
- Reduce the minimum requirement for carbohydrate in electrolyte drinks from 50 g/L to 20 g/L. This is to facilitate product innovation and allow manufacturers to develop healthier electrolyte drink options.
- Limit the maximum fructose permitted in electrolyte drinks to 50% of the total amount of carbohydrate to reflect the scientific evidence regarding both carbohydrate utilisation and the adverse effects of a high-fructose intake during physical activity.
- Prohibit health claims on electrolyte drinks, including self-substantiated health claims, other than three pre-approved health claims on electrolyte drinks with an average osmolality of 200-340 mOsm/kg, with specific requirements that the claims refer to effects occurring under conditions of strenuous physical activity for a minimum time period of 60 minutes to reflect these products’ intended purpose.
- Limit nutrition content claims on electrolyte drinks to their compositional constituents: carbohydrate; sugar or sugars; energy; and/or electrolytes (calcium, sodium, magnesium, potassium and chloride) to reflect these products’ intended purpose and reduce the potential for consumers to be misled.
- Prohibit % Recommended Dietary Intake (%RDI) declarations on electrolyte drinks to differentiate the addition of calcium and/or magnesium to function as electrolytes not minerals.
- Amend the units of osmolality to ‘per kilogram’ for compositional requirements, while retaining current labelling declaration unit requirements using ‘per litre’.

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<sup>1</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 Approval Report unless stated otherwise.

- Include a two year transition period to allow for the long shelf-life of electrolyte drinks, and to assist manufacturers to ready themselves to comply with the new requirements.

In summary, the amendments aim to provide regulatory clarity, support product innovation for the electrolyte drinks category within the Australia and New Zealand market and will better enable consumers to make informed choices. The amendments also reflect current public health policy to reduce the amount of sugar contained in sugar sweetened beverages.

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

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

# 1 Introduction

## 1.1 Proposal background

Food Standards Australia New Zealand (FSANZ) originally prepared Proposal P1030 in 2014 after gazettal of Standard 1.2.7 – Nutrition, Health and Related Claims of the Australia New Zealand Food Standard Code (the Code). P1030 sought to permit formulated supplementary sports foods (FSSF), 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 FSSF 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 a 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 FSSF
- make other minor amendments to improve the consistency of the regulation of electrolyte drinks in 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 in 2014, seeking submissions on that assessment and draft variation.

## 1.2 The modified Proposal

The market context has changed since the release of the P1030 Call for Submissions 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 doing so are unable to position these products as electrolyte drinks. A number of responses to the 2014 Call for Submission 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> had requested FSANZ review Standard 2.9.4 as a priority, for which FSANZ has prepared Proposal P1010.

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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 Approval Report 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 referred to as the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum).

Given these contextual changes, and after considering submissions received in response to the 2014 Call for Submission, FSANZ proposed to narrow the scope and direction of Proposal P1030. A Consultation Paper was released in 2021 which outlined the key matters under consideration related to composition and 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 included:

- reducing the minimum amount of carbohydrate required in electrolyte drinks, based on scientific evidence, with consequential changes to tonicity criteria
- restricting nutrition content claims to reflect the prescribed composition of electrolyte drinks
- prohibiting health claims on electrolyte drinks, including self-substantiated health claims, other than for three specific permitted health claims associated with the intended purpose of electrolyte drinks for hydration and maintenance of performance
- addressing the therapeutic nature of the existing health claim in Standard 2.6.2
- addressing FSANZ’s previous commitment to consider two European Union (EU) authorised health claims for ‘carbohydrate electrolyte solutions’ for use in Australia and New Zealand.

Several minor changes, some proposed in 2014, were further considered in the 2021 Consultation Paper, 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 Standard 2.6.2. FSANZ also proposed the regulation of electrolyte drinks remain in Standard 2.6.2, while recognising the classification of electrolyte drinks and transfer of these provisions within the Code may be further considered under Proposal 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**

<b>Component</b>	<b>Compositional Requirements</b>
(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 nutrition content and health claims on foods and sets out the conditions under which such claims can be made. This 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.

Section 2.3.5 below provides more details of the Code's labelling requirements that apply to electrolyte drinks.

#### **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, 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 Reasons for preparing the Proposal**

The Proposal was prepared to assess whether several existing regulatory conditions warranted variation. See Section 1.1 above.

### **1.6 Procedure for assessment**

The Proposal was assessed under the General Procedure of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

### **1.7 Decision**

For the reasons listed in this report, the draft variation as proposed following assessment was approved with amendments. Each of the amendments is explained in Section 2 below.

The approved draft variation is at Attachment A and will take effect on gazettal. The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

The draft variations on which submissions were sought are at Attachments C and D.

## **2 Summary of the findings**

In making its decision, FSANZ had regard to submissions received in 2014 on the draft variation and to submissions received in 2021 on a proposed amended version of that draft variation.

### **2.1 Summary of the 2014 submissions**

FSANZ received 39 responses to the P1030 2014 Call for Submissions. The issues raised are detailed and considered in the 2021 Consultation Paper (see Table 2 and Section 2.3 of that Paper). They are also considered below.

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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)

## **2.2 Summary of the 2021 submissions**

A total of 17 submissions were received in response to the 2021 Consultation Paper: seven from the industry sector, five from public health groups and five from government agencies. The relevant documents and submissions received are published on the FSANZ website.

In general, submitters supported use of the term 'electrolyte drink' as a prescribed name; removal of the term 'minerals' from the definition of electrolyte drinks; listing mineral salts as electrolytes; amending osmolality requirements; and updating requirements for providing nutrition information. For all other issues, including the regulation of nutrition content and health claims, stakeholder views were divergent across and within different sectors.

The issues raised in the 2021 submissions and the FSANZ response are provided in Table 1.

**Table 1: Summary of issues from 2021 submissions**

Issue	Raised by	FSANZ response
<b>Code placement</b>		
<p>Regard electrolyte drinks as special purpose/functional foods whose requirements align more closely with existing provisions contained within Standard 2.9.4.</p> <p>Do not support Health Star Rating (HSR) on electrolyte drinks – HSR can be used if they remain in Standard 2.6.2.</p>	<p>Victorian Department of Health            Western Australia Department of Health            New Zealand Food Safety            New Zealand Food and Grocery Council            Tasmanian Department of Health</p>	<p>FSANZ's position is to retain the current regulations in Standard 2.6.2. See Section 2.4.1 below.</p> <p>Transfer of these provisions to Standard 2.9.4 and the reclassification of electrolyte drinks as special purpose foods will, if required, be further considered in the review of Standard 2.9.4 (Proposal P1010).</p>
<b>Definition</b>		
<p><b>'Represented as'</b></p> <p>Consider the inclusion of both 'represented as' and 'formulated as' would assist differentiation between electrolyte drinks and other sports drinks for enforcement purposes. Also suggest the term 'is suitable for' could replace both 'represented as' and 'formulated for'.</p>	<p>Victorian Department of Health</p>	<p>FSANZ does not agree for the reasons listed in Section 2.4.2.1 below.</p>
<p><b>'Carbohydrate'</b></p> <p>Recommend the term 'carbohydrate' should be retained to:</p> <ul style="list-style-type: none"> <li>• improve consistency between the definition and purpose;</li> <li>• reflect the mandatory compositional requirements of electrolyte drinks given that the draft variation does not permit electrolyte drinks with zero carbohydrate; and</li> <li>• recognise its role in hydration and energy/performance.</li> </ul>	<p>Australian Beverages Council Limited            Australia Food &amp; Grocery Council            Dietitians Australia            New Zealand Beverages Council            New Zealand Food &amp; Grocery Council</p>	<p>FSANZ has reviewed the definitional components and decided to retain the term 'carbohydrate' in the definition of an 'electrolyte drink' to ensure that definition aligns with all the compositional requirements for electrolyte drinks. See Section 2.4.2.2 of this Report.</p>

Issue	Raised by	FSANZ response
<p><b>Time reference</b> Argue the inclusion of a '60 minutes' time limitation is overly prescriptive, and suggest 'sustained strenuous physical activity' is appropriate to inform consumers when to consume.</p> <p>Suggest the time duration should be extended to 90 minutes to:</p> <ul style="list-style-type: none"> <li>• align with Sports Dietitians Australia (SDA) recommendation</li> <li>• further highlight that electrolyte drinks are unnecessary for most individuals.</li> </ul>	<p>Australian Beverages Council Limited New Zealand Beverages Council</p> <p>Cancer Council of Australia Obesity Policy Coalition</p>	<p>FSANZ's position remains that the reference in the 'electrolyte drink' definition to the 60 minute time frame is appropriate and warranted. The 60 minute timeframe is based on evidence reviewed by FSANZ and the European Food Safety Authority (EFSA) of the relationship between consumption of electrolyte drinks and hydration/water absorption, and physical performance under conditions of strenuous exercise of 60 minutes or more.</p> <p>FSANZ notes the SDA factsheet is targeted at sports drinks, with most containing 6-8% carbohydrate. FSANZ's assessment considered the effects of hydration and performance at levels of carbohydrate less than 6% (minimum of 2% carbohydrate). The conditions specified on SDA's factsheet for sports drinks may therefore not be applicable to electrolyte drinks regulated under Standard 2.6.2.</p>
<p><b>Conditions of use</b> There is sufficient evidence to demonstrate a hydration benefit prior to/before exercise. Recommend reference to consuming electrolyte drinks prior to/before physical exercise, noting there is sufficient evidence to demonstrate a benefit to hydration and fuel status.</p>	<p>Australian Beverages Council Limited Australia Food &amp; Grocery Council New Zealand Beverages Council</p>	<p>Not supported. FSANZ's risk assessment reviewed the evidence under conditions of strenuous exercise for 60 minutes or more, <u>not</u> prior to/before exercise.</p>
<p><b>'Immediately after'</b> The term 'immediately after' should be included in reference to the 60 minutes timeframe.</p>	<p>Dietitians Australia</p>	<p>Not supported. FSANZ maintains the view that the proposed wording adequately captures the intended use, particularly when considered in the context of the wording in the definition ('during or after 60 minutes or more of sustained strenuous physical activity'). The word 'immediately' may also not be clear or provide clarification in this context.</p>

Issue	Raised by	FSANZ response
<p><b>Other</b></p> <p>Type of exercise should be defined as ‘vigorous’ to align with Australian physical activity guidelines.</p> <p>Suggest the proposed wording around intended use is a little ambiguous and could be taken to mean ‘for rapid hydration in activity under or over 60 minutes’, instead of clarifying these products are only effective for longer bouts of exercise.</p> <p>‘During or after’ is ambiguous and could be adjusted to ‘that lasts 60 minutes or more’.</p> <p>Suggest inclusion of the word ‘constant’ to inform consumers these products are meant to aid recovery from high intensity continual physical activity.</p>	<p>Cancer Council of Australia</p> <p>Victorian Department of Health</p> <p>New South Wales Food Authority</p>	<p>Not supported. FSANZ maintains the view that the proposed wording adequately reflects and is consistent with the nature of the product being regulated. The definition is not designed to inform consumers about the product.</p>
<b>Composition</b>		
<p><b>Minimum carbohydrate</b></p> <p>Recommend a more extensive review of the carbohydrate content of electrolytes including the:</p> <ul style="list-style-type: none"> <li>• types of carbohydrate</li> <li>• minimum and maximum carbohydrate range</li> <li>• to capture all products currently that are available in the market and to meet the needs of all end users.</li> </ul>	<p>Tasmanian Department of Health</p> <p>Sports Dietitians Australia</p>	<p>The risk assessment in SD1 included a review of all studies that assessed the effect of electrolyte drinks (5-10% CHO), with a similar drink with less than 5% carbohydrate that fulfilled the current definition of electrolyte drinks in the Code.</p> <p>The types of carbohydrate and the maximum threshold were beyond the scope of this Proposal and therefore did not form part of the risk assessment.</p>

Issue	Raised by	FSANZ response
<p><b>Maximum Fructose</b>  Opposition to the proposed variation to reduce the maximum amount of fructose permitted in electrolyte drinks from 50 to 20g/L with suggestions to align the reduction relative to the amount of total carbohydrate.</p>	<p>Australian Beverages Council Limited  Australia Food &amp; Grocery Council  Dietitians Australia  New Zealand Food &amp; Grocery Council  New Zealand Food Safety  Sports Dietitians Association</p>	<p>FSANZ has reconsidered this issue and decided to set the maximum fructose amount relative to the amount of total carbohydrate (i.e. no more than 50%). This amendment will ensure consistency between the permitted total carbohydrate and fructose amounts, and reflects the scientific evidence regarding both carbohydrate utilisation during sustained physical activity and the associated adverse gastrointestinal effects of high fructose intakes during physical activity. FSANZ notes this change will also facilitate innovation within the lower carbohydrate electrolyte drinks category  For further information see Section 2.4.3.2 of this Report.</p>
<p><b>Addition of other substances</b>  Question whether the draft variation would permit the addition of other nutritive substances or ingredients (including caffeine), and what impact this may have on both efficacy and/or product differentiation for enforcement purposes.</p>	<p>New Zealand Food Safety  Victorian Department of Health</p>	<p>The draft variation does not of itself permit the use of other nutritive substances or ingredients in electrolyte drinks. Existing provisions within Section 1.1.1—10 of the Code prohibiting the use of any substance as a nutritive substance, food additive or processing aid will continue to regulate their use in electrolyte drinks. The regulation of caffeine by the Code is being considered by FSANZ in Proposal P1056. This clarification is further discussed in Section 2.4.3.4 of this Report.</p>
<p><b>Labelling</b></p>		

Issue	Raised by	FSANZ response
<p><b>Prescribed name</b> Support a prescribed name but recommend it should be changed to 'sports drinks' to provide further clarity by reducing ambiguity, contextualising product use, promoting consistency with other government publications and making education easier.</p> <p>Note as a new mandatory labelling requirement this requirement should trigger a WTO notification.</p>	<p>Dietitians Australia Sports Dietitians Association</p> <p>New Zealand Food Safety</p>	<p>FSANZ considers the term 'electrolyte drink' captures the true nature of beverages that are targeted for a specific purpose and have a prescribed composition. FSANZ notes 'electrolyte drink' is often used by manufacturers on labels, who are required to include a name or description of the food sufficient to indicate the true nature of the food. The term 'sports drinks' commonly refers to a broader category of beverages which may share some similarities with electrolyte drinks, but do not fully reflect the specific intended purpose of electrolyte drinks. i.e. for the rapid hydration/rehydration during or after 60 minutes or more of sustained strenuous physical activity.</p> <p>A WTO notification was not deemed necessary given there are currently no international standards pertaining to electrolyte drinks (see Section 1.4 above). Mandating a prescribed name is unlikely to create any unnecessary obstacles to and/or have a significant effect on international trade particularly given the term 'electrolyte drink' is already widely used voluntarily by international companies.</p>

Issue	Raised by	FSANZ response
<p><b>Nutrition content claims</b></p> <p>Recommend no restrictions on nutrition content claims.</p> <p>Seek permission to make other nutrition content claims, if requirements are met for those claims. Standard 1.2.7 sets clear parameters around claims and if these are met, claims should be able to be made.</p> <p>No other product category has such stringent restrictions and it will hamper innovation if other nutrition content claims are not permitted.</p> <p>Nutrition content claims about the types and amounts of specific carbohydrate used are relevant to the speed of hydration and therefore helpful for consumers</p> <p>Athletes needs may extend beyond carbohydrate and electrolytes. Denying consumers information to make an informed chose.</p>	<p>Australian Beverages Council Limited Australia Food &amp; Grocery Council New Zealand Beverages Council New Zealand Food &amp; Grocery Council</p>	<p>FSANZ re-affirmed its approach to only allow nutrition content claims relating to the prescribed composition (i.e. about carbohydrate, sugar or sugars, energy or electrolytes) to reduce the potential for claims to mislead consumers about the purpose of electrolyte drinks. See Section 2.4.5.3 below.</p> <p>Mandatory declaration of nutrition information (see Section 2.4.5.2 of this Report) provides for informed consumer choice.</p>
<p><b>Nutrition content claims for prescribed electrolytes</b></p> <p>The ability for other beverages to make electrolyte claims and be marketed in a way that may give consumers the impression they are electrolyte drinks remains. Notably, 'Zero carbohydrate' drinks can legitimately contain electrolytes and make claims regarding their presence under the formulated beverages requirements. Recommend placing requirements for making electrolytes claims in Standard 1.2.7 to allow the compositional requirements to be added to Schedule 4 which would apply across all foods.</p>	<p>New Zealand Food Safety</p>	<p>Some 'prescribed electrolytes' are also minerals elsewhere in the Code, including Standard 1.2.7 and Schedule 4 (refer Section 2.4.5.3 of this Report). FSANZ therefore considers that conditions for nutrition content claims for prescribed electrolytes as they relate to electrolyte drinks should be regulated under Standard 2.6.2.</p> <p>The use of claims about electrolyte(s) on other beverages falls outside the scope of this Proposal. However, as discussed in Section 2.4.5.1 below, requiring the prescribed name 'Electrolyte drink' will provide certainty for product identification to avoid confusion with other similar beverages.</p>

Issue	Raised by	FSANZ response
<p>Seek clarification whether there is a need for permitted electrolytes to be added at a minimum level of 10% of the RDI (meets a 'source' status) or whether any amount can be added while being able to declare 'contains electrolytes'.</p>	<p>Australia Food &amp; Grocery Council</p>	<p>For nutrition content claims about prescribed electrolytes the conditions in Standard 1.2.7 and Schedule 4 would not apply. This includes the percent RDI conditions for vitamins and minerals in Schedule 4. See Section 2.4.5.3 of this Report.</p>
<p><b><i>Self-substantiation of health claims</i></b>            Strongly reject prohibition of self-substantiated health claims.            The self-substantiation process incentivises industry to: reformulate, provide broader consumer choice and respond to both evolving consumers' needs and public health policy recommendations.            A prohibition on self-substantiated health claims is restrictive and disadvantages electrolyte drinks over any other product category and suggest the restriction is removed.            It will restrict the growth of scientific evidence re: electrolyte drinks in sports performance and potentially discourage use of the electrolyte drink standard.            The requirements of Standard 1.2.7 would facilitate evidence based self-substantiated health claims.</p>	<p>Australian Beverages Council Limited            Australia Food &amp; Grocery Council            New Zealand Beverages Council            New Zealand Food &amp; Grocery Council            New Zealand Food Safety</p>	<p>After consideration of submissions, FSANZ's position remained that only three pre-approved health claims associated with the intended purpose of electrolyte drinks for hydration and maintenance of performance should be permitted. See Section 2.4.5.4 of this Report.</p>

Issue	Raised by	FSANZ response
<p><b>Pre-approved health claims</b> Should be broadened to include hydration prior to strenuous physical activity, together with carbohydrate and energy and energy for normal metabolism health claims as per Schedule 4–3.</p>	<p>Australian Beverages Council Limited Australia Food &amp; Grocery Council New Zealand Food &amp; Grocery Council</p>	<p>FSANZ is permitting three pre-approved health claims based on findings of the assessment undertaken by FSANZ (SD1) and EFSA as the evidence base for amending the current claim permission for electrolyte drinks. The evidence for the two EU authorised claims for carbohydrate electrolyte solutions to: enhance the absorption of water during physical exercise and contribute to the maintenance of endurance performance during endurance exercise has been reviewed and supported by EFSA, for electrolyte drinks containing ~1.9-8.4% carbohydrate. FSANZ's assessment considered data from human studies that compared the effect of consuming electrolyte drinks with different carbohydrate content during and after exercise on rehydration and performance. Consideration of other conditions and/or other health effects relating to electrolyte drink consumption (including effects on metabolism) were not included in the assessment.</p>
<p><b>Loss of 'availability of energy' part of the existing health claim</b> No scientific rationale was provided to justify the removal of the current permission to promote the availability of energy nor was the effect of carbohydrate on energy a measured outcome in SD1. Advise higher carbohydrate (≥5%) electrolyte drinks are consumed for both hydrating and energising benefits, depending on individual dietary needs and the environment under which they're exercising in. Suggest consumers should be able to easily identify electrolyte drinks intended for both hydrating and refuelling.</p>	<p>Australian Beverages Council Limited</p>	<p>Electrolyte drinks will continue to be permitted to carry nutrition content claims about energy and carbohydrate in accordance with Standard 1.2.7. The permitted health claims have been based on assessment findings by FSANZ (SD1) and EFSA as the evidence base for amending the current claim permission for electrolyte drinks. The evidence for the two EU claims for carbohydrate electrolyte solutions relate to absorption of water and maintenance of endurance performance. FSANZ's assessment compared the effect of consuming electrolyte drinks with different carbohydrate content during and after exercise on rehydration and performance. The effects of energy on performance were not included in the assessment.</p>

Issue	Raised by	FSANZ response
<p><b>Evidence for pre-approved health claims</b>  Evidence supporting the pre-approved claims is not deemed equivalent to that requirements of Schedule 6 for self-substantiated claims.  Acknowledge this is a rapidly evolving area of scientific research and note the evidence from EFSA is already 10 years old and may be therefore outdated.</p>	<p>New Zealand Food Safety  Department of Health Tasmania</p>	<p>Both sources of evidence reviewed by FSANZ and by EFSA were considered by FSANZ before proposing amendment of the current claim permission. Both reviews considered the relationships between consumption of electrolyte drinks and hydration/water absorption, and electrolyte drinks and physical performance. For further discussion of this issue refer to Section 2.4.5.4 of this Report.</p>
<p><b>Flexibility on wording of claims</b>  Proposed wording (reference to a time period of 60 minutes or more) is overly prescriptive.  Industry is seeking greater flexibility and suggest this could be achieved by a reference to effects occurring under conditions of ‘sustained strenuous physical activity’.</p>	<p>Australian Beverages Council Limited  Australia Food &amp; Grocery Council  New Zealand Beverages Council  New Zealand Food &amp; Grocery Council</p>	<p>FSANZ has included a quantified time to describe the minimum time for strenuous activity to provide guidance on the appropriate use of electrolyte drinks. The time period of 60 minutes is based on scientific evidence reviewed by FSANZ and EFSA.</p>
<p><b>Claim conditions</b>  The term ‘strenuous’ should be replaced by ‘vigorous’ to align with the Australian physical activity guidelines.  Suggest the term ‘prolonged’ should be included immediately before ‘strenuous physical activity’.  Including ‘immediately after’ in reference to ‘60 minutes or more of sustained strenuous physical activity’ would provide further clarification.  Health claim qualifiers need to be clearly visible and understandable to consumers to ensure they are not misinterpreted to apply to hydration in general nor to imply the product is healthy or beneficial for all consumers.</p>	<p>Cancer Council of Australia  Dietitians Australia  Sports Dietitians Association  Australian Medical Association</p>	<p>Reference to 60 minutes or more of strenuous activity is consistent with FSANZ’s assessment. Inclusion in the permitted health claim makes clear to consumers that hydration benefits only apply for those undertaking strenuous physical activity of at least 60 minutes in duration.  Consistent with the existing provisions relating to the existing health claim in Standard 2.6.2, the wording that must be used when making a health claim based on the three approved health claims is not prescribed.</p>

Issue	Raised by	FSANZ response
<p><b>Performance claim</b> The 'hydration to maintain performance' claim is not specific enough to meet the Ministerial Policy Guideline on Nutrition, Health and Related Claims, which states that 'claims must communicate a specific benefit' (e.g. improves recovery from exercise rather than improves sports performance)'. </p>	<p>Tasmanian Department of Health Victorian Department of Health</p>	<p>All three pre-approved claims relate to rapid hydration or re-hydration as the specific health effect. FSANZ notes the construct of the preapproved claim:  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.'  is similar to other pre-approved claims included in Schedule 4 of the Code. That is 'rapid hydration contributes to maintenance of performance'.</p>
<p><b>Claim presentation</b> Request flexibility on the requirement for claims to be placed elsewhere on the pack, within an advertisement, or the ability to split the claim across the packaging.</p>	<p>Australia Food &amp; Grocery Council</p>	<p>Standard 2.6.2 does not prescribe how the existing claim for electrolyte drinks is expressed. This allows for flexibility in presentation of this information. FSANZ is making no changes to the requirements for presentation of claims under Standard 2.6.2.</p>
<p><b>Mandatory Statements</b> Suggest information for intended use of electrolyte drinks should be presented as a mandatory statement/advisory statement, not via a voluntary health claim. The use of mandatory statements would be consistent with sports foods and in line with the specialised purpose of electrolyte drinks and the risks they pose to consumers. Note this approach would also be consistent with ministerial policy guidance for special purpose foods which states adequate information (including through labelling) should be provided to help prevent inappropriate use by those for whom the special purpose food is not intended.</p>	<p>Tasmanian Department of Health Victorian Department of Health</p>	<p>FSANZ considers that including the intended use of electrolyte drinks as part of a health claim rather than as a mandatory statement is the appropriate level of risk management for addressing the potential for consumers to be misled about the intended purpose and use of electrolyte drinks.</p>

Issue	Raised by	FSANZ response
<p><b><i>Nutrient Profile Scoring Criterion (NPSC) should be extended to nutrition content claims</i></b>  The NPSC should be extended to all products carrying nutrition content claims to ensure consumers are not misled by claims on energy dense, nutrient poor foods and drinks.</p>	<p>Cancer Council of Australia</p>	<p>The scope of P1030 is only electrolyte drinks. To extend the NPSC to all nutrition content claims is out of scope.</p>
<p><b><i>NPSC should not apply to electrolyte drinks</i></b>  Consider it is not appropriate for electrolyte drinks to meet the NPSC in order to allow general level health claims.</p>	<p>New Zealand Food Safety</p>	<p>FSANZ's decision is to permit three pre-approved health claims for electrolyte drinks. Standard 1.2.7 does not apply to a health claim made about an electrolyte drink or electrolyte drink base, including the requirements to meet the NPSC.  Refer Section 2.4.5.4 of this Report for information on the approach for health claims.</p>
<b>Electrolytes</b>		
<p><b><i>Prohibit %RDI declarations</i></b>  There is merit in reconsidering the exemption from declaring %RDI as electrolytes, by their compositional chemistry, are still minerals under Schedule 17 and therefore contribute to dietary exposure to minerals.</p>	<p>New South Wales Food Safety Authority</p>	<p>The requirements for RDIs in the Code are based on their function in the body as minerals. FSANZ considers that percentage RDI declarations are not relevant in the context of electrolyte drinks that have an intended purpose and prescribed composition. Consumers can still readily access information regarding the amount of added minerals (electrolytes) from the NIP.</p>

Issue	Raised by	FSANZ response
<p><b>Identification of prescribed electrolytes</b></p> <p>If a claim is made for a specific electrolyte, listing electrolytes in the NIP as Sodium (electrolyte) would provide greater clarity for consumers and help enforcement agencies assess compliance.</p> <p>Seek clarification on the difference fulfilled by electrolytes with an associated health benefit from their technological purpose in foods as additives. This may aid consumer and enforcement understanding.</p>	<p>New Zealand Food Safety New South Wales Food Safety Authority</p>	<p>The prescribed electrolytes will be identified in Standard 2.6.2, which can be referred to for enforcement purposes. Nutrition content claims are required to include the word 'electrolyte', which will provide clarity to consumers.</p> <p>Prescribed electrolytes are permitted to be added to electrolyte drinks for the purposes of rapid replacement of fluid and electrolytes (refer to Section 2.3 of this Report). These substances are also permitted to be used as a food additive in electrolyte drinks with the maximum permitted level of GMP to perform a particular technological function in the food (refer definition of GMP in Standard 1.1.2 of the Code).</p>
<b>Transition Period</b>		
<p>Seek a longer transition period given the number of other labelling changes required to be implemented by the beverage industry, the long shelf-life of electrolyte drinks and the direct impact on trade/imported supplies as a direct consequence of COVID-19.</p>	<p>Australian Beverages Council Limited Australia Food &amp; Grocery Council New Zealand Beverages Council New Zealand Food &amp; Grocery Council New South Wales Food Authority</p>	<p>FSANZ has amended the drafting to allow for a longer transition period. See Section 3 of this Report for further discussion.</p>

## **2.3 Risk assessment**

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 the assessment 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.

It was 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). The full assessment is included at Supporting Document 1 (SD1).

## **2.4 Risk management**

### **2.4.1 Code placement**

#### *Proposed approach in 2014*

The draft variation prepared in 2014 transferred 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 D). This was based on FSANZ's assessment at that time, that such a transfer recognised and emphasised the product's special purpose in accordance with its regulatory definition, while noting it was a preliminary step prior to the wider review of Standard 2.9.4.

FSANZ received mixed support from submitters in 2014. Submissions cited 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 the need for such a transfer pending the comprehensive review of Standard 2.9.4 that would consider that Standard's application to electrolyte drinks. One jurisdiction noted regulation of electrolyte drinks by Standard 2.9.4 would not reflect the actual range of population usage. All jurisdictions stressed the need for any regulatory change to be underpinned by a robust scientific evidence base.

#### *Proposed approach and amendments in 2021*

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

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

#### *FSANZ's decision*

After consideration of submissions, FSANZ's position remained that Standard 2.6.2 is the appropriate location in the Code for electrolyte drink permissions at this time. As noted above, transfer to Standard 2.9.4 and reclassification of electrolyte drinks as special purpose foods as part of Proposal P1010 remains an option. Given the complexity of issues to be assessed under P1010, sufficient time will be required to complete that Proposal.

### **2.4.2 Definition**

#### *Current definition*

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.

#### *Proposed approach in 2014*

The drafted variation prepared in 2014 proposed the following definition:

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

FSANZ's assessment in 2014 was that the requirement for electrolyte drinks to be 'represented as' relied on voluntary labelling including health claims which had become superfluous. FSANZ's position was that the draft variation's definition strengthened the association of consumption of electrolyte drinks with their intended purpose for use in relation to sustained strenuous physical activity.

FSANZ also removed the reference to minerals from the draft variation's definition because – at that time - there was no mandatory compositional requirement to include minerals, other than sodium. Sodium could be considered as an electrolyte and is treated as such in certain tables in Schedule S29 – Special purpose foods.

Government submitters in 2014 supported the revised definition including those who sought further alignment between the definition and the permitted claim. One industry submitter at that time opposed omitting 'represented as' because, in its view, enforcement would be

easier for regulators based on labelling representations rather the compositional requirements.

Some submitters in 2014 sought definitions of particular terms in the revised definition for: sustained strenuous exercise, rapid replacement, and electrolyte (and in the Standard 2.9.4 context – no longer considered – sports person, and achieving specific nutritional or performance goals).

#### *Proposed approach and amendments in 2021*

The 2021 Consultation Paper proposed amending the draft variation's definition to reflect additional proposed compositional and labelling changes also proposed in 2021. The proposed definition in 2021 was:

***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<sup>8</sup>.

This revised definition included a number of changes to the existing definition of electrolyte drink.

Submitters in 2021 generally agreed to remove the term 'minerals'. However there were mixed views in relation to the other definitional components, as discussed below.

#### **2.4.2.1 'Formulated for'**

##### *Proposed approach and amendments in 2021*

In the 2021 Consultation Paper, FSANZ confirmed the amendment proposed in 2014 to only refer to 'formulated for' rather than including 'represented as' in the definition to more closely align with the compositional requirements of Standard 2.6.2. FSANZ also noted no enforcement agencies had expressed concern or provided evidence in previous submissions regarding any inability to enforce the Code.

In responding to the 2021 Consultation Paper, one government submitter suggested the inclusion of both 'represented as' and 'as formulated' or, alternatively replacing both with the term 'is suitable for' to ensure sufficient differentiation between electrolyte drinks and other sports drinks for enforcement purposes. No other jurisdiction proposed such an amendment.

##### *FSANZ's Decision*

After consideration of submissions, FSANZ decided not to adopt the submitter's suggested amendments.

FSANZ considered that including the two terms in the definition would likely impede enforcement activity in that regulators would need to establish that the product is both *formulated* and *represented as*. Doing so sets a higher level of compliance and imposes a greater regulatory burden for enforcement agencies. It may also create a potential regulatory gap if a *drink formulated for the rapid replacement of fluid and electrolytes* after the required period of *sustained strenuous physical activity* is not *represented as* an electrolyte drink at sale. It could be argued in this case that the drink is not 'an electrolyte drink' for the purpose of the Code. Subsequently, it would not be subject to any of the Code requirements that apply to or will apply to products that meet the Code's definition of an electrolyte drink.

FSANZ did not consider the term 'is suitable' to be a viable alternative as it would be difficult to contextualise what 'suitable' means in this context, noting the definition would need to be applied by and form part of the Food Acts which contain their own separate *unsuitable* food offence provisions. Requiring regulators to establish that a product is suitable in order to prove that the Code requirements for electrolyte drinks apply to that product would appear

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<sup>8</sup> The word 'sustained' was unintentionally left out of the definition in the draft variation, however it was intended that the definition referred to 'sustained strenuous physical activity', as discussed in Section 2.3.2.2 of the Consultation Paper.

likely to create a greater evidentiary burden for regulators than only determining ‘formulated for’. Furthermore, it could create a tautology in that only drinks that are first *suitable* for ‘the rapid replacement of fluid and electrolytes during strenuous physical activity that lasts 60 minutes or more’ must comply with separate legal compositional and other requirements designed to ensure that such drinks are in fact *suitable* for that purpose.

As noted above, replacing the term ‘represented as’ with ‘formulated for’ affords for alignment with the compositional requirements in Standard 2.6.2. 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 an ‘electrolyte drink’ would have to meet the electrolyte drink requirements in Standard 2.6.2.

The mandatory prescribed name will also assist electrolyte drinks to be easily identified for enforcement purposes.

#### **2.4.2.2 ‘Carbohydrate’**

##### *Proposed approach and amendments in 2021*

In the 2021 Consultation Paper, FSANZ proposed amending the definition in the 2014 draft variation to remove the term ‘carbohydrate’. This was on the basis that the minimum required carbohydrate content for electrolyte drinks was also being reduced and, as a result, both carbohydrate’s replacement and contribution as an energy source should no longer be given prominence.

Industry submitters in 2021 opposed this on the grounds summarised in Table 1 above.

##### *FSANZ’s decision*

After consideration of submissions, FSANZ decided to include the term ‘carbohydrate’ in the definition. This reference will strengthen the link between the intended purpose and definition and the role of carbohydrate in hydration and performance. Its retention also reflects the mandatory compositional requirements in totality, noting the definition does not allow for zero carbohydrate electrolyte drinks.

#### **2.4.2.3 Minimum time reference**

##### *Proposed approach and amendments in 2021*

In the 2021 Consultation Paper, FSANZ proposed amending the definition in the 2014 draft variation to include a minimum time period of 60 minutes. This was to clarify what is meant by sustained strenuous physical activity.

There was in-principle support from government and public health submitters in 2021. However, industry submitters viewed the reference to this time period as overly prescriptive and sought its removal (see Table 1 above).

Several government and public health submitters in 2021 also suggested alternative wording for the definition to clarify intended use including:

- substituting ‘during or after 60 minutes or more’ with ‘that lasts 60 minutes or more’
- inclusion of the word ‘constant’
- replacing the term ‘sustained’ with ‘vigorous’, and
- inserting ‘immediately after’ with reference to the 60 minutes timeframe.

##### *FSANZ’s decision*

After consideration of submissions, FSANZ decided to retain the 60 minute minimum time reference. The reference was based on the scientific evidence provided in SD1 to this

Report. FSANZ considers its inclusion necessary as it provides clarity for both target and non-target end users to more clearly identify the intended purpose.

After consideration of submissions, FSANZ decided to not to adopt the above-mentioned suggested alternative wording. The meaning of the terms *strenuous* and *rapid replacement*, were left to their ordinary and commonly understood meanings. FSANZ's assessment was that the wording of the amended definition in its entirety adequately captures the intended use.

#### **2.4.2.4 Final wording**

For the reasons outlined above, FSANZ approved a draft variation with the following definition:

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

### **2.4.3 Composition**

#### **2.4.3.1 Minimum carbohydrate level**

##### *Proposed approach in 2014*

The 2014 proposal did not consider changing the minimum level of carbohydrate in electrolyte drinks.

One industry submitter in 2014 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.

##### *Proposed approach and amendments in 2021*

In the 2021 Consultation Paper, FSANZ proposed amending the 2014 draft variation to reduce the minimum permitted carbohydrate for electrolyte drinks to 20 g/L while retaining the maximum carbohydrate at 100 g/L. Section 2.3.3.2 of the 2021 Consultation Paper lists FSANZ's reasons for doing so.

In general, stakeholders supported the amendment to reduce the minimum carbohydrate. Submissions received in response to the 2021 Consultation Paper noted this would both permit and encourage manufacturers to provide consumers with healthier electrolyte drink options. It also results in greater product capture of electrolyte drinks currently in the market whilst aligning with current carbohydrate intake guidelines during exercise. In addition, submitters considered the variation would reduce the sugar content of electrolyte drinks, therefore contributing to a reduced sugar intake, for those consumers who opt for the lower carbohydrate product.

Several submitters suggested a more comprehensive review to encompass the various types of carbohydrate with others recommending an expansion of the minimum and maximum concentrations ( $\leq 2$  to  $\geq 10\%$ ). FSANZ notes that these elements were beyond the scope of this Proposal.

##### *FSANZ's decision*

FSANZ decided to proceed with this amendment. This approach is consistent with the risk assessment conclusion 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 (Section 2.3 and SD1). In addition, the variation is supported by dietary guidelines in Australia and New

Zealand that recommend limiting intake of foods containing added sugars and reflects current initiatives to reduce the sugar content of sugar sweetened beverages.

#### **2.4.3.2 Maximum fructose level**

##### *Proposed approach and amendments in 2021*

In conjunction with lowering the minimum permitted carbohydrate amount to 20 g/L, FSANZ also proposed in the 2021 Consultation Paper that the draft variation be amended to reduce the current maximum fructose amount from 50 g/L to 20 g/L.

Industry submitters opposed the amendment (see Table 1 above).

##### *FSANZ's decision*

After consideration of submissions, FSANZ opted to amend the maximum fructose threshold and set it relative to the amount of total carbohydrate (i.e. no more than 50% of total carbohydrate). This will ensure consistency between the permitted total carbohydrate and fructose amounts, whilst reflecting the scientific evidence of both carbohydrate utilisation during sustained physical activity, and the negative effects of high fructose ingestion on gastrointestinal tolerance during physical activity. See also FSANZ's response in Table 1 above.

#### **2.4.3.3 Food additives**

As noted in the 2021 Consultation Paper, the proposed reduction in the amount of carbohydrate may result in intense sweeteners being more commonly used to enhance 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 in 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.

#### **2.4.3.4 Addition of other substances**

In responding to the 2021 Consultation Paper, two submitters sought clarification as to whether the draft variation would permit the addition of other nutritive substances or ingredients (including caffeine), and what impact this may have on both efficacy and/or product differentiation for enforcement purposes.

The amendments made by the draft variation set compositional requirements for an electrolyte drink and list specific substances that an electrolyte drink must or may contain. None of the amendments of themselves expressly prohibit the addition to an electrolyte drink of any other nutritive substance or ingredient.

Other provisions of the Code regulate the addition of other nutritive substances or ingredients to electrolyte drinks. Section 1.1.1—10 of the Code provides that a food for sale must not contain, as an ingredient or a component, a substance that has been used as a nutritive substance unless expressly permitted by the Code. This means that an electrolyte drink must not contain a nutritive substance as an ingredient or component unless that the use or presence is expressly permitted by the Code. Section 1.1.1—10 imposes a similar prohibition for substances used as food additives or as processing aids.

The above also means that caffeine cannot be present in an electrolyte drink as a result of being used as a nutritive substance, food additive or processing aid unless that use, addition or presence is expressly permitted by the Code. FSANZ is not aware of any relevant express permissions in the Code allowing the use, addition or presence of caffeine in an electrolyte

drink as a nutritive substance, food additive or processing aid. FSANZ also notes the New Zealand High Court's consideration of the above-mentioned provisions in its decision in 2012 that the Code did not permit the addition of caffeine to an electrolyte drink as a food additive.

The regulation of caffeine by the Code is being considered by FSANZ in Proposal P1056 – Caffeine Review.

#### **2.4.4 Osmolality**

##### *Proposed approach and amendments in 2021*

In 2021, FSANZ proposed an amendment to 2014 draft variation that, commensurate with the lower minimum carbohydrate permission for electrolyte drinks, would reduce the lower threshold of the average osmolality range to 200 mOsm/kg while retaining the maximum osmolality of 340 mOsm/kg. Section 2.3.5.2.2 and page 22 of the 2021 Consultation Paper list the reasons for this amendment.

Submitters supported the amendment. Submitters also agreed that the units of measure for osmolality for should be changed from /L to /kg for all compositional requirements. Section 2.3.5.5 below discusses claims in relation to tonicity.

##### *FSANZ's decision*

FSANZ decided to proceed with this amendment.

#### **2.4.5 Labelling**

##### **2.4.5.1 Electrolyte drink as a prescribed name**

##### *Proposed approach in 2014*

The draft variation prepared by FSANZ in 2014 proposed to prescribe the name 'Electrolyte drink' for electrolyte drinks and electrolyte drink bases. The reason was to help clearly identify electrolyte drinks for enforcement purposes. As mentioned in Section 1.3.4 above, 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.

There were very few comments about this from submitters in 2014. One government submitter supported the proposed approach whereas an industry submitter opposed it. The latter argued there was no demonstrated need for a prescribed name and that the requirement for a prescribed name would warrant WTO notification.

##### *Proposed approach and amendments in 2021*

In the 2021 Consultation Paper, FSANZ maintained the approach proposed in 2014. Section 2.3.9.2 of the Consultation Paper listed FSANZ's reasons for doing so.

All submitters in 2021 supported this approach, acknowledging it is advantageous for identification purposes in providing clarity for both consumers and enforcement agencies. 'Electrolyte drink' is also commonly used on labels of electrolyte drinks to meet the current requirements of Standard 1.2.2–2 which requires manufacturers to include a name or description sufficient to indicate the true nature of the food. See also FSANZ's response in Table 1 above on this issue and in Section 2.4.2 below.

##### *FSANZ's decision*

FSANZ therefore has decided to prescribe the name 'Electrolyte drink' for electrolyte drinks and electrolyte drink bases to provide certainty for product identification, 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.

## **2.4.5.2 Nutrition information requirements**

### *Current requirements*

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 packaged food (unless exempted) to 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.

### *Proposed approach in 2014*

The draft variation proposed for the 2014 Call for Submissions 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 industry submitter in 2014 supported the amendments. Another industry submitter opposed them on the basis that the above would require energy, electrolytes and carbohydrate to be declared in the NIP, including for small packages which was currently not the case.

### *Proposed approach and amendments in 2021*

In the 2021 Consultation Paper, the general approach for NIPs on electrolyte drinks remained the same, however the requirements remained in Standard 2.6.2. In summary, the requirements proposed in 2021 were as follows:

- Retain current requirements in Standards 1.2.1 and 1.2.8 to label foods with an NIP to electrolyte drinks.
- Retain current requirement in subsection 2.6.2—11(2) to declare the recommended volume and frequency of use on the labels of electrolyte drinks.
- The NIP to declare average quantity per serving and per unit quantity of each type of monosaccharide and disaccharide present.
- In addition to the generic requirement in Standard 1.2.8 to declare the average quantity of sodium in the NIP, require the average quantity per serving and per unit quantity of other prescribed electrolytes (chloride, calcium, magnesium and potassium) that is present in the electrolyte drink to be declared in the NIP, i.e. the amount of each prescribed electrolyte derived from all sources<sup>9</sup>.
- Require electrolytes to be declared in milligrams (mg) with the optional additional use of millimoles (mmol).

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<sup>9</sup> 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.

- Exempt electrolyte drinks from the requirement to declare the %RDI of minerals (calcium and magnesium) (section 1.2.8—9) and prohibit referring to %RDI in relation to an electrolyte drink.
- Not apply the requirement in subsection 1.2.8—6(12) to declare the average quantity of potassium of the food if a nutrition content claim is made about sodium.
- Apply the existing requirements in Standard 1.2.1 for NIPs to electrolyte drinks exempt from the requirement to bear a label (under subsection 1.2.1—6(1)).

For electrolyte drinks in a small package, the requirements proposed in 2021 were as follows:

- Apply the current exemption from the requirement to include a NIP (in Standard 1.2.8) on the label.
- Require declaration of the average quantity per serving of each electrolyte present (in mg with additional use of millimoles optional) if a nutrition content or health claim is made about prescribed electrolytes.
- Not apply the requirements in paragraph 1.2.8—14(1)(b), and therefore Schedule 13 for nutrition content and health claims about electrolytes on electrolyte drinks sold in a small package. This included the requirements in Schedule 13 to declare, for example:
  - the %RDI of minerals (calcium and magnesium)
  - potassium when a claim about sodium is made
  - sodium when a claim about potassium is made.

FSANZ's rationale for the above approach is detailed in Section 2.3.7.2 of the 2021 Consultation Paper.

The majority of submitters in 2021 supported the approach for nutrition information requirements as proposed in the Consultation Paper.

#### *FSANZ's decision*

After consideration of submissions, and for the reasons stated in the 2021 Consultation Paper, FSANZ decided to maintain the approach as outlined above.

### **2.4.5.3 Nutrition content claims**

#### *Current requirements*

Nutrition content claims about electrolyte drinks can currently be made in accordance with Standard 1.2.7.

#### *Proposed approach in 2014*

No changes were proposed to the regulation of nutrition content claims for electrolyte drinks in 2014.

One submitter in 2014 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 at that time 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.

#### *Proposed approach and amendments in 2021*

In the 2021 Consultation Paper, FSANZ proposed prohibiting all nutrition content claims about electrolyte drinks except for claims about: carbohydrate; sugar or sugars; energy; or the presence of one or more prescribed electrolytes (calcium, sodium, magnesium, potassium and chloride). As stated in Section 2.3.4.2 of the Consultation Paper, the rationale for this approach was to limit nutrition content claims to those associated with the intended purpose and prescribed composition of electrolyte drinks, and to reduce the potential to

mislead consumers about the purpose and place of electrolyte drinks in the diet. The approach also aligned with that proposed for health claims, that is to only permit electrolyte drinks to carry health claims relating to their intended purpose.

Submitters in 2021 were split in their views on the proposed approach. A number of submitters raised concern that the approach for nutrition content claims is overly restrictive and will hamper innovation. Other submitters supported the approach to restrict nutrition content claims in line with their intended purpose. See Table 1 above.

#### *FSANZ's decision*

After consideration of submissions, FSANZ decided to maintain the approach in the Consultation Paper for nutrition content claims for the reasons stated in the Consultation Paper. That is, to limit nutrition content claims about electrolyte drinks to only claims about carbohydrate, sugar or sugars, energy or the presence of one or more prescribed electrolytes.

The permission for sugar/s claims will allow for 'reduced sugar' type claims, noting the compositional approach to reduce the minimum carbohydrate content in electrolyte drinks as discussed in Section 2.3.3.1 above. Further, as explained in Section 2.3.3.5 above, section 1.1.1- 10 applies to electrolyte drinks to prohibit the addition of nutritive substances unless expressly permitted. Therefore if in the future there is a change to the prescribed composition of electrolyte drinks by allowing the addition of other nutritive substances, additional nutrition content claim permissions can be considered at this time.

Nutrition content claims about carbohydrate, sugar and sugars, and energy will have to comply with the applicable conditions in Standard 1.2.7 and Schedule 4. For nutrition content claims about prescribed electrolytes (calcium, sodium, magnesium, potassium and chloride) the conditions in Standard 1.2.7 and Schedule 4 will not apply. The conditions for magnesium and calcium claims as minerals in Schedule 4 are not considered appropriate as these are based on a 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.

Nutrition content claims about the presence of prescribed electrolytes will be permitted and can refer either to electrolytes generally, for example 'contains electrolytes', or to individual prescribed electrolyte(s), for example, 'contains the electrolytes: calcium and sodium'. For a nutrition content claim about individual prescribed electrolytes, the claim will 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 2.3.5.2 for requirements for the declarations of electrolytes in the NIP).

#### **2.4.5.4 Health claims**

##### *Current requirements*

Section 1.3.2 above explains the current requirements for health claims relating to electrolyte drinks.

##### *Proposed approach in 2014*

The draft variation prepared in 2014 would permit electrolyte drinks 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. Electrolyte drinks carrying health claims would not be required to meet the NPSC, consistent with the approach for special purpose foods and the proposal at that time for electrolyte drinks to be regulated as a special purpose food by Standard 2.9.4 (see Section 2.3.1 above). 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 retained.

Submissions in 2014 were mixed. Some supported the proposed approach or elements of the proposed approach, whereas others did not. Table 2 and Section 2.3.5 of the 2021 Consultation Paper provide a summary of the issues and arguments raised by submitters. FSANZ had regard to these in making its decision in 2021.

#### *Proposed approach and amendments in 2021*

In the 2021 Consultation Paper FSANZ proposed to prohibit health claims on electrolyte drinks other than for three specific claims. The proposed health claims for electrolyte drinks with an average osmolality of 200–340 mOsm/kg were:

- 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’.

It was proposed that Standard 1.2.7 and Schedule 4 would not apply to a health claim made about electrolyte drinks, including the permission for self-substantiated health claims.

The rationale for this approach was to reduce the potential for consumers to be misled about the benefits of electrolyte drinks and their place in the diet (refer Section 2.3.5.2 of the Consultation Paper). The approach also reflected the current situation whereby most electrolyte drinks are not able to make health claims according to Standard 1.2.7 (as they do not meet the NPSC), but would provide specific relevant claims associated with the purpose of electrolyte drinks. The proposed claims would also replace the existing therapeutic claim permission in subsection 2.6.2—12(3). It was also noted that the overall approach for health claims about electrolyte drinks would, if required, be reconsidered in the broader context of the regulation of sports foods under P1010.

The proposed health claims for electrolyte drinks were informed by an EFSA opinion for two EU-authorized claims as well as sources of evidence reviewed by FSANZ and by EFSA. The risk assessment undertaken by FSANZ (see SD1) reviewed the comparative difference between electrolyte drinks above and below 5% carbohydrate with respect to hydration and performance. Both FSANZ and EFSA reviewed the evidence under conditions of strenuous exercise for 60 minutes or more, but neither undertook a full systematic review.

FSANZ previously considered EU claims under P293 – Nutrition, health and related claims, during the development of Standard 1.2.7, where a number of EU claims were adopted for inclusion in Schedule 4 without a systematic review. Two authorised EU claims relating to carbohydrate electrolyte solutions were deferred for further consideration in this Proposal<sup>10</sup>.

The scientific rationale and the conditions for the EU health claims are given in Appendix 1 to this report. 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. Details of the amended claims wording, including reasons for inclusions, changes and deletions, are explained in Section 2.3.5.2.2 of the 2021 Consultation Paper.

As in 2014, submitters in 2021 expressed polarised views. Most public health and government submitters supported the prohibition on health claims and generally supported permitting specific claims with conditions for their intended purpose. Conversely, most industry submitters and one government submitter expressed opposition to the approach for

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

health claims, in particular the restriction on self-substantiated health claims. See Table 1 above.

#### *FSANZ's decision*

After consideration of submissions and noting the diverse stakeholder views, FSANZ decided to re-affirm the approach in the 2021 Consultation Paper for health claims. That is, to prohibit health claims on electrolyte drinks, including self-substantiated health claims, other than three pre-approved claims relating to the intended purpose of electrolyte drinks for hydration and maintenance of performance. The rationale remained that as stated in the Consultation Paper. The prohibition in effect reflects the current situation whereby most electrolyte drinks are not able to make health claims according to Standard 1.2.7 (as they do not meet the NPSC), but rely on the permission in Standard 2.6.2 to make a specific health claim (see Section 1.3.2 above). The approach taken addresses concerns about the potential for consumers to be misled about the intended purpose and use of electrolyte drinks.

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

##### *Current requirements*

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

##### *Proposed approach in 2014*

No changes were proposed to this approach in 2014.

##### *Proposed approach in 2021*

In the 2021 Consultation Paper FSANZ proposed to make no changes to the current osmolality range defining isotonic claims (250–340 mOsmol/L) except for a change to the units (refer Section 2.3.3.3 above).

All submissions to the Consultation Paper supported this approach.

#### *FSANZ's decision*

FSANZ has therefore decided to maintain the approach in the 2021 Consultation Paper.

A claim that an electrolyte drink is isotonic may only be made if the electrolyte drink has an average osmolality of 250–340 mOsmol/kg. For compositional requirements the units of osmolality will be mOsm/kg however current labelling declaration unit requirements of osmolality using mOsm/L are retained if a claim is made that the drink is isotonic, hypertonic or hypotonic.

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 insignificant when rounding is taken into account (no more than about 3%).

#### **2.4.6 Existing definitions in the Code**

A number of definitions in section 1.1.2—3 of the Code, as applicable to Standard 2.6.2 are also included in section 2.6.2—2 as a Note to that section.

##### *Proposed approach in 2021*

In the draft variation in the 2021 Consultation Paper, additional definitions relevant to the new draft variation, that are already in sections 1.1.2—2, 1.1.2—3 and 1.1.2—9(1), were also

included in section 2.6.2—2, as Notes 1, 2 and 3 respectively.

#### *Decision*

The approach in the draft variation outlined above has been maintained with the exception of the nutrition content claim definition. This definition was inadvertently included in both Notes 1 and 3 and has therefore been removed from Note 1.

### **2.4.7 Risk management conclusion**

Overall, FSANZ concludes that the changes to the prescribed composition and labelling requirements for electrolyte drinks within Standard 2.6.2 of the Code as outlined above will provide regulatory clarity and reduce the potential for consumers to be misled about the intended purpose and place of electrolyte drinks in the diet. The amendments also reflect current public health policy to reduce the amount of sugar contained in sugar sweetened beverages.

## **2.5 Risk communication**

### **2.5.1 Consultation**

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this Proposal. A call for submissions was issued in 2014 and called from 18 August 2014 to 30 September 2014. A public Consultation Paper also called for submissions from 28 May 2021 to 9 July 2021. Thirty nine submissions were received in 2014. Seventeen submissions were received in 2021. Subscribers, interested parties and members of the public were notified about the public consultation period via the FSANZ Notification Circular, a media release, FSANZ's social media tools and Food Standards News.

In its assessment and finalisation of this Proposal, FSANZ had regard to all submissions received.

FSANZ acknowledges the time taken by individuals and organisations to make a submission. All comments are valued and contribute to the rigour of our assessment.

### **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 create any unnecessary obstacles to and/or have a significant effect on international trade. The mandatory prescribed name 'electrolyte drink' is widely used voluntarily by international companies and the reduced carbohydrate compositional requirement will expand the potential category range for manufacturers. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade Agreement was not deemed necessary.

## **2.6 FSANZ Act assessment requirements**

### **2.6.1 Section 59**

When assessing this Proposal and in the development of an approved draft food regulatory measure, FSANZ had regard to the following matters in section 59 of the FSANZ Act:

#### **2.6.1.1 Consideration of costs and benefits**

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) granted FSANZ an exemption from the requirement to develop a Regulation Impact Statement (RIS) for this Proposal (OBPR correspondence dated 14 May 2021, OBPR ID:43269). This exemption was provided as the OBPR assessed the currently proposed variation is deregulatory and the likely impacts to only have a minor effect on consumers, businesses and government.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure 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 29(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 will better enable consumers to make informed decisions and access greater 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 amended draft variation is less prescriptive and allows more pre-approved health claims about hydration and performance than are currently permitted, and these 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.

The proposed amendments may require other label changes in addition to the prescribed name, associated with changes to nutrition and health claims and potentially NIPs as well. Therefore, after public consultation in 2021 it has been decided to extend the proposed transition period from 12 months to 24 months to minimise industry label change costs.

#### *Government*

The proposed mandatory prescribed name would assist enforcement agencies to identify electrolyte drink products from other water-based beverages. Approving this amended draft variation would therefore provide greater regulatory certainty and may reduce overall enforcement costs, although more electrolyte drinks may need to be monitored for compliance.

#### *Conclusions from cost benefit considerations*

FSANZ's assessment is that the direct and indirect benefits that would arise from approving the amended draft variation, are likely to outweigh the associated costs to the community, government and industry.

Information on the market value and volume of sports drinks is provided at Supporting Document 2 of this Report.

#### **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 the 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 Standards.

#### **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.

##### **2.6.2.1 Protection of public health and safety**

The consumption of electrolyte drinks represents only 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 following proposed amendments will help safeguard public health and safety:

- reduction in minimum carbohydrate (sugars) from 5% to 2%
- restrictions on nutrition content claims
- prohibition on health claims, other than three specific claims which must include a reference to 60 minutes or more of strenuous physical activity (which will aid to identify the target/non-target group).

These amendments will permit manufacturers to provide consumers with healthier electrolyte drink options than currently available. The above regulatory measures also support current public health policy.

##### **2.6.2.2 The provision of adequate information relating to food to enable consumers to**

### ***make informed choices***

Existing generic labelling requirements in the Code would continue to apply to electrolyte drinks in addition to the changes as discussed above in Sections 2.4.5.1 (prescribed name) and 2.4.5.2 (nutrition information requirements).

These labelling requirements will clarify the intended purpose 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 the approved draft variation will, for the reasons discussed above, assist in achieving this objective. In particular, the prohibition on making nutrition content and health claims other than the limited claims permitted relating to the intended purpose of electrolyte drinks will help to prevent consumers from being misled about the nature and use of electrolyte drinks.

#### **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 2.3 above and SD1) in relation to all measures proposed in the amended draft variation. These measures include revising the composition and labelling requirements for electrolyte drinks; and revising the requirements and limitations for nutrition content 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**

The approved draft variation would allow for a competitive food industry in relation to electrolyte drinks. Reducing the minimum carbohydrate compositional requirement and extending the permission for (amended) health claims to electrolyte drinks with the lower carbohydrate content and the inclusion of hypotonic electrolyte drinks, in addition to isotonic, will remove potential barriers to internationally traded electrolyte drinks.

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

No specific issues were identified for this Proposal relevant to this objective. FSANZ considers that its requirement to permit electrolyte drinks to only carry specified claims consistent with their intended purpose, will support fair trading.

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

The Ministerial policy guideline on Nutrition, Health and Related Claims<sup>11</sup> is relevant to this regulatory measure.

The new provisions permit 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

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

conditions for nutrition content and health claims incorporated into Standard 2.6.2 under this Proposal.

### **3 Transitional arrangements**

In the 2021 Consultation Paper, FSANZ proposed a 12 month transition period commencing on the date of gazettal would apply to electrolyte drinks, in keeping with the Code's default standard transition arrangements provided by section 1.1.1—9 of the Code.

FSANZ has since reconsidered this time period and is now proposing the approved draft variation will take effect on the date of gazettal, with a two year (24 month) transition period.

FSANZ considers a longer transition period is more appropriate given required labelling changes that will directly impact the electrolyte drinks category and beverage manufacturers generally. This change is commensurate with the transition periods recently afforded to other applications and proposals requiring possible compositional and label changes, and recognises both the relatively long shelf-life of electrolyte drinks and the myriad of challenges industry are experiencing as a result of Covid-19.

During the transition period, an electrolyte drink can comply with either the Code as in force as if the variation had not taken effect, or with the Code as amended by the variation. After the two year transition period, all electrolyte drinks in the Australian and New Zealand market would have to comply with the approved draft variation.

### **4 Implementation and review**

As mentioned above, the review of Standard 2.9.4 (Proposal P1010) provides an opportunity, if required, to review and further consider the amendments made by the approved draft variation.

#### **Appendices**

- 1 EU Health Claims for Electrolyte Drinks
- 2 Electrolyte drink market, consumption and consumer research

#### **Attachments**

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variation to the *Australia New Zealand Food Standards Code* (consultation paper)
- D. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

## 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>12</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>12</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>13</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>14</sup>.

<sup>13</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>14</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)

## **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.
- 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 – Approved draft variations 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 24 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, carbohydrate and electrolytes during or after 60 minutes or more of sustained 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).

**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, carbohydrate and electrolytes during or after 60 minutes or more of sustained 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 50% of total carbohydrate as 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 mOsmol/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 – Explanatory Statement

### 1. 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 originally 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 call for submissions (CFS) draft variation).

The Authority then called for submissions on the draft variation in 2014 under section 61 of the FSANZ Act and had regard to all submissions made during the CFS in accordance with subsection 63(2) of the Act. Consequently, the Authority had 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 Authority also proposed that the regulation of electrolyte drinks and electrolyte drink bases would remain in Part 2.6 of the Code and not be transferred to Part 2.9 as originally proposed. Following further consideration of the Proposal in accordance with Division 2 of Part 3, the Authority proposed a number of amendments to the draft variation.

The Authority undertook further consultation with stakeholders in May 2021 on the proposed amendments to the draft variation and has had regard to all submissions made during that consultation in addition to submissions received in 2014. The Authority then further considered the Proposal in accordance with Division 2 of Part 3 of the FSANZ Act and approved the draft variation with amendments (the approved draft variation).

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation (also known as the Food Ministers' Meeting), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

### 2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation ([www.legislation.gov.au](http://www.legislation.gov.au)).

This instrument is not subject to the disallowance or sunseting provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunseting if the enabling legislation for the instrument (in this case,

the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunseting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

### **3. Purpose**

The Authority has approved a draft variation that amends Standards 1.1.2, 1.2.1 and 2.6.2 of the Code to enhance 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 claims that may be made in relation to electrolyte drinks and electrolyte drink bases, such as nutrition content claims and health claims.

### **4. Documents incorporated by reference**

The approved draft variation does not incorporate any documents by reference.

### **5. Consultation**

The Authority's consideration of Proposal P1030 included two rounds of public comment: a call for submissions issued in accordance with the procedure in Division 2 of Part 3 of the FSANZ Act; and a subsequent public consultation paper. The first detailed and sought submissions on: the Authority's assessment; the draft variation prepared as a result of that assessment; and associated reports. The second sought submissions on the Authority's further assessment after consideration of submissions received and on a proposed amended draft variation. Submissions were called for on 18 August 2014 and again on 28 May 2021; each for a six-week duration.

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). As the Proposal had undergone significant change in direction since the CFS in 2014, FSANZ sought further advice from the OPBR, who subsequently confirmed they are satisfied that the amendments to the draft variation proposed post CFS are deregulatory and likely to only have a minor effect on consumers, businesses, and government (ID: 43269).

### **6. 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 44 of the *Legislation Act 2003*.

## 7. Variation

### Standard 1.1.2 – Definitions used throughout the Code

**Item [1]** of the Schedule to the variation 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, carbohydrate and electrolytes during or after 60 minutes or more of sustained strenuous physical activity.’

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

**Item [2]** of the Schedule to the variation amends Standard 1.2.1. The item amends the reference in paragraph 1.2.1—8(1)(t) to declarations and 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]** of the Schedule to the variation 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 Division 4 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) sets out the mandatory compositional requirements for electrolyte drinks and electrolyte drink bases. This subsection 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 50% of total carbohydrate as fructose.

Subsection 2.6.2—11(3) sets out the discretionary compositional requirements for electrolyte drinks and electrolyte drink bases. This subsection 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 1.1.2—2(3) [see **subitem 3.2** of the approved draft variation]. The labelling provisions in Standard 1.2.1 and section 1.2.2—2 require 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 (NIP) must also declare the average quantity per serving and per unit quantity of all of the following (paragraph 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 approved draft variation].

There are *Notes* to paragraph 2.6.2—12(2)(b).

*Note 1* explains that labelling provisions are set out in Standard 1.2.1.

*Note 2* explains that section 1.2.8—5 provides that packaged food (unless exempted) must include an NIP; and Standard 1.2.8 also contains other requirements relating to NIPs, for example, information that must be included and how to express that information in an NIP (see sections 1.2.8—6 and 1.2.8—7). This *Note* also explains that 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) requires that an NIP 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—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.

The effect of both subparagraph 2.6.2—12(2)(b)(iii) 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—i.e., 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 ‘small package’ and ‘claim requiring nutrition information’ are defined in subsection 1.1.2—2(3) [see **subitem 3.2** of the approved 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.

There are two *Notes* to subsection 2.6.2—13(2).

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

*Note 2* 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 a claim requiring nutrition information that is made about a prescribed electrolyte. 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). Subsection 2.6.2—13(3) provides that these nutrition information requirements do not apply when a claim requiring nutrition information is made about a *prescribed electrolyte* in an electrolyte drink or electrolyte drink base in a small package.

The *Note* to subsection 2.6.2—13(3) 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.

The *Note* to subsection 2.6.2—14(2) explains that section 1.2.8—9 relates to minerals with an RDI (among other things). As stated above, 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, 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 made about electrolyte drinks and electrolyte drink bases.

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

Subsection 2.6.2—15(1) provides that a nutrition content claim must not be made about an electrolyte drink or electrolyte drink base unless 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.

'Sugar' is defined in subsection 1.1.2—2(2) and 'sugars' is defined in subsection 1.1.2—2(3) [see **subitem 3.2** of the approved draft variation].

Subsection 2.6.2—15(2) provides that if a nutrition content claim is made under subparagraph 2.6.2—15(1)(b)(iv) i.e., the claim 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 that 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 section 2.6.2—10 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 made 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 approved 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 approved 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 mOsm/kg.

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

The *Note* to subsection 2.6.2—17(2) 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.

The *Note* to section 2.6.2—18 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 NIP 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 24 month transition period commencing on the date of gazettal, an electrolyte drink or electrolyte drink base may be sold if the electrolyte drink or electrolyte drink base complies with either the Code as in force without the amendments made by the approved draft variation; or the Code as amended by the approved draft variation. The intent is to provide a 24 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 – Amended Draft variation to the *Australia New Zealand Food Standards Code* (consultation paper)



### 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 D – Draft variation to the *Australia New Zealand Food Standards Code* (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