Public Health Association of Australia
Submission to Food Standards Australia New Zealand on Proposal P1030 Health Claims – Formulated Supplementary Sports Foods & Electrolyte Drinks

30 September 2014
Contents

Introduction ........................................................................................................................................... 3

Public Health ......................................................................................................................................... 3

The Public Health Association of Australia .......................................................................................... 3

Advocacy and capacity building .......................................................................................................... 3

Preamble .................................................................................................................................................. 4

Response to specific components ........................................................................................................ 5

a) Permit FSSF and ED to carry health claims ....................................................................................... 5
   (i) Consistency with Government policies/initiatives to promote healthy food choices ............... 5
   (ii) Claims substantiation and enforcement ........................................................................................ 5

b) Move ED from Standard 2.6.2 to Standard 2.9.4 ............................................................................... 7
   (i) Definition of Special Purpose Food ............................................................................................... 7
   (ii) Targetting to population groups satisfying the definition ......................................................... 7

c) Review of current claims permissions ............................................................................................ 8

d) Need for an advisory statement ..................................................................................................... 9

Recommendations .................................................................................................................................. 10

Conclusion .............................................................................................................................................. 10

References ............................................................................................................................................... 11
Introduction

The Public Health Association of Australia Incorporated (PHAA) is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles. The PHAA has a vision for a healthy region, a healthy nation and healthy people living in a healthy society and a sustaining environment while improving and promoting health for all.

Public Health

Public health includes, but goes beyond the treatment of individuals to encompass health promotion, prevention of disease and disability, recovery and rehabilitation, and disability support. This framework, together with attention to the social, economic and environmental determinants of health, provides particular relevance to, and expertly informs the Association’s role.

The Public Health Association of Australia

PHAA is a national organisation comprising around 1900 individual members and representing over 40 professional groups concerned with the promotion of health at a population level. Key roles of the organisation include the development of policy, capacity building and advocacy. Core to our work is an evidence base drawn from a wide range of members working in public health practice, research, administration and related fields who volunteer their time to inform policy, support advocacy and assist in capacity building within the sector. PHAA supports a preventive approach for better population health outcomes by championing appropriate policies and providing strong support for Australian governments and bodies such as the National Health and Medical Research Council in their efforts to develop and strengthen research and actions in public health. The PHAA is an active participant in a range of population health alliances including the Australian Health Care Reform Alliance, the Social Determinants of Health Alliance, the National Complex Needs Alliance and the National Alliance for Action on Alcohol.

PHAA has Branches in every State and Territory and a wide range of Special Interest Groups. The Branches work with the National Office in providing policy advice, in organising seminars and public events and in mentoring public health professionals. This work is based on the agreed policies of the PHAA. Our Special Interest Groups provide specific expertise, peer review and professionalism in assisting the National Organisation to respond to issues and challenges as well as a providing a close involvement in the development of policies. In addition to these groups the PHAA’s Australian and New Zealand Journal of Public Health (ANZJPH) draws on individuals from within PHAA who provide editorial advice, and review and edit the Journal.

Advocacy and capacity building

In recent years PHAA has further developed its role in advocacy to achieve the best possible health outcomes for the community, both through working with all levels of governments and agencies, and promoting key policies and advocacy goals through the media, public events and other means.
Preamble

PHAA welcomes the opportunity to comment on P1030 and makes the following points, which will be expanded on further throughout the submission. PHAA does not support the proposal to:

- Permit Formulated Supplementary Sports Foods (FSSF) and Electrolyte Drinks (ED) to carry health claims nor retain the existing permitted claims
- Move ED from Standard 2.6.2 to Standard 2.9.4

Further, PHAA would recommend that this proposal be an opportunity to review the current claims permissions for these products as it is not clear what evidence was used to determine the varacity of the claims and so this is not in keeping with the intent of Standard 1.2.7 nor with the Section 18 FSANZ objectives.

In addition, if the proposed changes are approved, PHAA would recommend the inclusion of an advisory statement to assist with risk management and inform consumers that the products are not suitable for those not undertaking strenuous physical activity.

While we understand a review of 2.9.4 is planned, the scope and timing of the review are unclear – hence our need to raise some of the broader issues in relation to these products now.
Response to specific components

a) Permit FSSF and ED to carry health claims

(i) Consistency with Government policies/initiatives to promote healthy food choices

Sports drinks (EDs in particular) are classified along with sugar sweetened beverages as discretionary foods that should be limited in a healthy diet (1). The Guidelines stress that consumption of discretionary foods may be associated with development of obesity, other chronic diet-related diseases and tooth decay. EDs have a similar energy and added sugar content to sugar sweetened beverages (113kJ/7g sugar per 100g) and (140kJ/8.6g sugar per 100g) respectively. In addition, the Committee on Nutrition and the Council on Sports Medicine and Fitness have stated that “excessive caloric intake can result from routine dietary intake of carbohydrate-containing beverages such as sports drinks, energy drinks, or soft drinks. This excessive caloric intake can substantially increase the risk for overweight and obesity in children and adolescents and should be avoided.” (2) Foods carrying health claims are viewed by consumers as being healthier and the “halo” effect can discourage them from seeking further information (3). Allowing health claims on sports drinks is therefore inconsistent with government nutrition policy and advice to limit the intake of these foods. One of the government’s latest initiatives to provide clear, consistent information to allow comparisons of food items and selection of healthier choices is the Health Star Rating System. The scheme design took into account the need to align food labelling in Australia with the Australian Guide to Healthy Eating. Allowing additional health claims on EDs would represent a huge step backwards for consumer information in Australia and would weaken the positive initiatives currently being driven by government in consultation with industry and public health groups.

PHAA recommends that no further health claims be permitted on FSSF and that current permissions relating to functions be reassessed to include the most relevant and up to date evidence - see section c) overleaf.

(ii) Claims substantiation and enforcement

These beverages are already permitted to make claims in relation to their specified purpose, although it is unclear on what basis these permissions were previously granted. Additionally, the proposed amendment allows these current claims to be retained without reference to standard 1.2.7, thereby only requiring any new claims to be subject to the substantiation provisions of Standard 1.2.7.

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

PHAA would submit that this is not an anomaly – but a clearly intended component of the safeguards built into the standards to protect health, provide accurate information to consumers and prevent deception. Indeed, in the Final Assessment Report for P293 this very issue was
PHAA submission on Proposal P1030 Health Claims – Formulated Supplementary Sports Foods & Electrolyte Drinks

addressed by FSANZ, where it justified the rationale for not permitting health claims for foods in Part 2.9:

The suggestion by a submitter that the prohibition of claims not specifically permitted under Standard 2.9.4 be lifted will not be carried out under this Proposal. The removal of this prohibition, combined with the exemption from the nutrient profiling scoring criteria would effectively open up the opportunity for claims on these products without the need to meet any food vehicle eligibility criteria. A large range of Formulated Supplementary Sports Foods are sold in supermarkets in addition to specialty retail stores and these are often represented in a very similar way to general purpose foods. If such products were eligible to carry health claims without being subject to nutrient profiling scoring criteria they may be misleading as to the overall health value and purpose of this range of products, i.e. as a supplement to the diet to assist sports people to achieve specific nutritional or performance goals. This would also be inconsistent with the conditions for health claims for the rest of the food supply. Final Assessment report P293 (2008) Attachment 4


PHAA supports this interpretation and reiterates that the approach proposed is likely to create consumer confusion and is inconsistent with the intent of the requirement for foods to meet nutrition criteria (ie restriction on the use of health claims on products that are inconsistent with national nutrition guidelines) before they can carry claims. This requirement is a key component of Standard 1.2.7 as it recognises that health claims provide an overall impression of healthiness of food products displaying them and hence the necessity to ensure that these foods are indeed in keeping with nutrition guidelines.

Standard 1.2.7 in the Code provides for health claims to be made about foods, including health claims about physical performance, providing such foods meet certain claim criteria. Interestingly, none of the current 212 FSANZ pre-approved nutrition-health relationships relate to enhanced athletic performance. This will mean that manufacturers will need to self substantiate any claims relating to this relationship. This then raises potential enforcement issues – many of which were raised as part of P293, including:

Concern was raised in the review request that this approach would be difficult to enforce and be resource intensive for enforcement authorities. There was general support for FSANZ to undertake pre-market assessment of systematic reviews ….. The 2009 consultation paper proposed that food-health relationships be pre-approved by FSANZ with a list of pre-approved food-health relationships included in the draft Standard. This was to provide certainty that food-health relationships were valid, reduce the burden of enforcement and improve enforceability.

(17 February 2012 Call for submissions – Proposal P293 Nutrition, Health & Related Claims
PHAA submission on Proposal P1030 Health Claims – Formulated Supplementary Sports Foods & Electrolyte Drinks

The enforcement of manufacturer substantiated claims has not been reported on and so it is difficult to determine whether there are problems existing currently, but as more and more claims become manufacturer substantiated it could be predicted that enforcement agencies (which are already strained) may find it increasingly difficult to ensure claims are valid and accurate.

b) Move ED from Standard 2.6.2 to Standard 2.9.4

PHAA believes that this is purely an attempt to manipulate the positioning of EDs in order to make them exempt from meeting the NPSC if the proposal to allow an increased range of health claims on these particular products in Part 2.9 were to be successful. However, there are a number of reasons why regulation relating to EDs should not be transferred to Standard 2.9.4.

(i) Definition of Special Purpose Food

The Australia and New Zealand Ministerial Forum on Food Regulation Policy Guideline on the Intent of Part 2.9 – Special Purpose Foods states that this Part of the Code:

\[
\text{is intended to contain food standards that prescribe specific requirements for foods processed or manufactured for use by physiologically vulnerable individuals and population sub-groups..... where physiological vulnerability relates only to situations where there is risk of dietary inadequacy to support:}
\]

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

We would therefore argue that EDs do not meet this definition given that the stated definition proposed will be

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

There is nothing relating to requiring an altered energy intake in this definition.

The proposal also suggests that

the draft variation permits both FSSFs and EDs to carry health claims relating to their respective purposes i.e. for FSSFs, to assist sports people in achieving specific nutritional or performance goals; and for EDs, for the rapid replacement of fluid, carbohydrates and electrolytes lost as a result of sustained strenuous physical activity ...

Once again, no specific statement of the purpose being to deal with increased requirement for energy. We would therefore submit that EDs do not meet the requirements for being deemed a Special Purpose Food.

(ii) Targetting to population groups satisfying the definition

The Ministerial Policy guideline also states that food standards contained within Part 2.9 of the Code should maintain a clear distinction between special purpose foods and other foods as regulated elsewhere in the Code and that special purpose foods should be targeted only to those population groups satisfying the definition.
EDs are marketed to the general public in numerous ways (eg billboards, television, televised sport, sporting clubs etc) and are marketed to children as part of sport sponsorship deals (eg Powerade Junior Cricket program and Gatorade Under 18 Twenty20 Cup). Consumer research indicates that consumers believe EDs are aimed at the general market rather than elite athletes and although they do distinguish EDs and other soft drinks, they do so by believing they are a healthier option – which suggests they are already confused. Consumers do use these products as part of a general dietary intake for various reasons including taste, undertaking physical activity in hot temperatures and when feeling lethargic. Interestingly, consumers could distinguish the more specialized sports foods like FSSF as foods for specific sports purposes.

Indeed the companies manufacturing these products suggest they are not only for those who undertake sustained, strenuous exercise. See the following for statements made on 2 manufacturer’s websites.

**When should I drink Gatorade?**

Gatorade is not just for serious athletes, but can benefit all of us who enjoy being physically active.

**Why do people need electrolytes when they aren’t competing or working out?**

Athletes and active people sometimes do a poor job of rehydrating themselves. Electrolytes, particularly sodium, are critical for proper hydration, helping maintain electrolyte balance, and helping your body hold on to the fluid it needs.

**Children and Gatorade.**

Where can you purchase Gatorade for Active Under 13s and is it available in single format?

Currently, the product is sold in six packs in all leading supermarkets across the country. We hope to make the product available in more channels and formats over the coming months.


**11. Can I drink Staminade when I’m not exercising?**

Staminade is an excellent recovery and recuperation drink after an illness, diarrhoea attack or operation. Staminade will replace the electrolytes lost by your body during these times. But please consult your doctor for advice specific to your condition. Some doctors suggest Staminade is an excellent choice for pregnant women but again please seek your doctor’s advice.


We therefore suggest that the way EDs are currently marketed and the views that consumers hold regarding their use put them outside the scope of the Ministerial Policy Guidance.

c) **Review of current claims permissions**

Claims that isotonic electrolyte drinks are designed to promote the availability of energy or prevent or treat mild dehydration that may occur as a result of sustained strenuous exercise, are currently permitted in the Code in Standard 2.6.2.

In addition, Standard 2.9.4 permits particular FSSFs that meet one of three types of compositional specifications (high carbohydrate; protein energy, or energy) to carry certain claims on their labels.
PHAA submission on Proposal P1030 Health Claims – Formulated Supplementary Sports Foods & Electrolyte Drinks

e.g. the product is useful before, during and after sustained strenuous exercise. However, the standard also prohibits an express or implied representation that relates to any property or proposed use of the food to enhanced athletic performance or beneficial physiological effects – although presumably the “use” before, during and after sustained strenuous exercise might relate to performance in the minds of many users.

It is not clear how the existing claims permitted for FSSF and ED were assessed and therefore their degree of accuracy is questioned. Given the advent of Standard 1.2.7 which prescribes the process for substantiation of claims and the FSANZ objective to ensure the provision of adequate information relating to food to enable consumers to make informed choices, PHAA would strongly recommend that any current claim permissions not be automatically retained but undergo the substantiation process accordingly.

In the case of the current permitted claim for ED, FSANZ have previously stated that

This claim meets the definition of a health claim but would be prohibited under draft Standard 1.2.7 because it refers to the prevention of a condition (i.e. a ‘therapeutic’ claim). (From Final Assessment report 2008 Attachment 4)

So, even if EDs are permitted to carry health claims, this current claim would need to be modified.

Recently, the process of substantiation of sports foods used by the European Food Safety Authority (EFSA) has been called into question (4). It is reported that the Authority did not systematically assess the totality of the literature and instead relied on industry proffered research and they did not adequately determine the strength and quality of evidence. The authors then go on to discuss the evidence relating to 2 permitted claims in relation to enhancement of water absorption and maintenance of endurance and report a number of deficiencies such as poor scientific design of studies, low study numbers and poor sample selection. They go on to suggest that the approved claims could be readily challenged if complaints are brought to agencies such as those overseeing advertising standards.

A recent Australian study, using a double blind, randomised methodology tested the effectiveness of either placebo or a 6% carbohydrate capsule or beverage in a small sample of elite athletes. They found no difference in performance in a 60km cycle time trial (5).

These more recent studies suggest that the food-health relationships that are currently permitted to be claimed for both ED and FSSF need reassessment.

**d) Need for an advisory statement**

The Ministerial Policy Guideline states that -

Adequate information should be provided, including through labelling and advertising of special purpose foods, to:

- assist consumer understanding of the specific nature of the food, the intended population group and intended special purpose of the food; and

- provide for safe use by the intended population and to help prevent inappropriate use by those for whom the special purpose food is not intended.
Currently, FSSFs must carry advice that such foods are not suitable for pregnant women or children under 15 years of age; and that they must be used under medical or dietetic supervision. There is currently no advisory statement relating to the intended population either for EDs or FSSFs. Given the propensity of consumers to perceive EDs as equivalent - and even “healthier” than other non-alcoholic beverages, PHAA strongly recommends that an advisory statement such as “not suitable to those undertaking moderate exercise under 90 minutes in duration” or “suitable only for those undertaking strenuous exercise of 90 minutes or more” be required.

Recommendations

This submission from PHAA recommends:

- No further health claims be permitted on EDs and FSSF
- Regulation of EDs remain under Standard 2.6.2 to ensure that these products are subject to nutrient profile scoring criteria which will limit use of health claims
- Current permissions relating to functions be reassessed to include the most relevant and up to date evidence
- An advisory statement such as “not suitable to those undertaking moderate exercise under 90 minutes in duration” or “suitable only for those undertaking strenuous exercise of 90 minutes or more” be required on all EDs.

Conclusion

PHAA appreciates the opportunity to make this submission and looks forward to the possibility of further participation in the deliberations.

Please do not hesitate to contact PHAA should you require additional information or have any queries in relation to this submission.

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30 September 2014
References


5. Nassif C et al. The Effect of Double – Blind Carbohydrate Ingestion during 60 km of Self-Paced Exercise in Warm Ambient Conditions. PLOS One, 2014; 9(8).