

FSANZ Proposal P1030 Health Claims – Formulated Supplementary Sports Foods & Electrolyte Drinks

SUBMISSION from Food Safety and Nutrition Branch, SA Health 30 September 2014

SA Health welcomes the opportunity to comment on P1030 which aims to deliver an interim arrangement pending the future review of Standard 2.9.4, and proposes to:

- permit formulated supplementary sports foods (FSSFs), electrolyte drinks and electrolyte drink bases (EDs) to carry health claims consistent with their intended purposes related to exercise or physical performance and in accordance with Standard 1.2.7 – Nutrition, Health and Related Claims;
- transfer the regulation of EDs from Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drinks to Standard 2.9.4 – Formulated Supplementary Sports Foods.

Issues of concern

SA Health has the following concerns about this proposal.

1) Validity of stated anomaly

The proposal states that the Code prevents FSSFs and EDS from carrying health claims consistent with their specific purposes except for a very limited number of claims, and that the proposal would address this anomaly. SA Health questions whether this is actually a valid anomaly given FSANZ's previous position and recommendations regarding health claims for sports foods when Standard 1.2.7 was being developed.

In the Final Assessment Report for Proposal P293 – Nutrition, Health and Related Claims, FSANZ was against lifting the prohibition of claims not specifically permitted under Standard 2.9.4 on the basis that claims would be allowed without having to meet the NPSC and may therefore be misleading, and inconsistent with the conditions for health claims for the rest of the food supply.¹ FSANZ then recommended in the above mentioned report that the ability for FSSFs to make health claims beyond those already permitted by Standard 2.9.4 be considered under the review of Standard 2.9.4 rather than Proposal P293. **SA Health considers that to permit new health claims as per P1030 without a full review of Standard 2.9.4 is inconsistent with FSANZ's previously stated recommendation, and recommends that the status quo is maintained until a full review of 2.9.4 has been conducted.**

A key safeguard of health claims under Standard 1.2.7 is that they are designed to be restricted for use on products that meet the Nutrient Profiling Scoring Criteria (NPSC) in support of the Australian Dietary Guidelines for the general population. This is a different context to that which informed the current permitted claims developed for use on FSSFs and EDs as special purpose foods for specific population groups. **This tension needs to be further explored via a full review of Standard 2.9.4 before assuming that the existing health claims should**

continue to be permitted for FSSFs and EDs, let alone altering 2.9.4 to allow new health claims for these products without NPSC applying.

- 2) The need to fully review 2.9.4 and the proposed ED definition to adequately reflect evidence based FSSF and ED products in the current market place, and consider the rationale for ongoing permissions for health claims on these products.

In the interest of a more comprehensive and accurate Standard 2.9.4, SA Health recommends maintaining the status quo for the interim whilst a full review of Standard 2.9.4 for FSSFs is undertaken, rather than proceeding with the interim arrangements proposed in P1030. The rationale for this includes:

- There is a need for Standard 2.9.4 to reflect FSSFs in the current market place based on sound and current evidence for their effectiveness in improving sports performance, and safe usage. A full review of Standard 2.9.4 would allow an update of the evidence base for the wide array of FSSFs now on the market; consider if health claims should be permitted at all for FSSFs and EDs (including review of the international regulations and experience in this area); and ensure a consistent approach to the proposed wording for allowable claims only for sub-categories of these products where the evidence supports it.
 - There is now a vast array of FSSFs on the market with many subcategories, and varying evidence of their effectiveness in improving sports performance. The Australian Institute of Sport (AIS) Sports Supplement Framework (SSF) ABCD Classification system ranks sports foods and supplement ingredients into four groups based on scientific evidence and other practical considerations that determine whether a product is safe, legal and effective in improving sports performance.² The AIS Sports Supplement Panel provides oversight of the Framework and reports directly to the Australian Sports Commission.
 - AIS SSF Group A category supplements (supported for use in specific situations in sport using evidence-based protocols) alone include:³
 - *sports foods* such as sports drinks, sports gels, sports confectionery, liquid meal replacements, whey protein, sports bars, and electrolyte replacements;
 - *'performance supplements'* (e.g. caffeine, B-alanine, bicarbonate, beetroot juice, creatine)
 - *medical supplements* to assist clinical issues including diagnosed nutrient deficiencies (e.g. multivitamins, vitamins, minerals, probiotics).
 - A small number of foods and ingredients or food components fall into Group B (i.e. products deserving of further research and only recommended for specific athletes participating in research or clinical monitoring situations). A large number of FSSF products on the market fall into Group C category (i.e. products that have little meaningful proof of beneficial effects). A number of other food components are listed in Group D (banned or at high risk of contamination with substances that could lead to a positive drug test).
 - **It is important that Standard 2.9.4 does not inadvertently allow health claims to be used on FSSFs undeserving of such claims due to weak**

evidence, or allow health claims on FSSFs that are associated with producing positive drug tests.

- This is further reinforced given the European experience. Recently, the validity of the European Food Safety Authority's (EFSA) methods to evaluate self-substantiated health claims for sports drinks was found to be deficient in terms of scientific evidence and scientific rigour.⁴ For example EFSA did not assess the quality of study designs, types of evidence or outcomes in relation to improved sporting performance. EFSA accepted evidence from manufacturers of sports drinks regarding effectiveness of their own products. Submissions also included book chapters, opinion articles, non-systematic review articles as well as scientific studies. If further health claims are permitted, FSANZ should ensure adequate rigour around evidence required for self-substantiation, and its assessment, as required for Standard 1.2.7.
- Any revision of Standard 2.9.4 with regard to EDs should include consideration of the full scope of EDs in the market place, i.e. regular EDs and 'zero sugar' EDs (e.g. Powerade Zero: an electrolyte enhanced sports drink with zero sugar that focuses on rapid hydration without carbohydrate replacement).⁵ This current proposal only considers regular sugar based EDs in its definition of EDs and ED bases, not 'no added sugar' EDs.
- Some sports confectionery (i.e. highly concentrated sources of carbohydrate (75-90%) in a chewy jelly bean/jube form)⁶ and sports gels (65-70% carbohydrate)⁷ also contain electrolytes and caffeine. Caffeine or electrolytes do not currently appear to be permitted in FSSFs under 2.9.4.
- In summary a full review on 2.9.4 should include:
 - review of FSSF and ED categories and nutritional profile definitions to ensure products in the current market place can be appropriately categorized;
 - consider if health claims should be permitted at all for FSSFs and EDs (including review of the international regulations and experience in this area)
 - a review of FSSFs that have substantiated evidence to support improved sporting performance -this could be partly informed by the Australian Institute of Sport's Supplement ABCD Classification Framework.

3) Labelling concerns

1. Consistent and clearly defined terminology should be used in any revision to Standard 2.9.4

Any revision of Standard 2.9.4 should ensure there is use of consistent wording in the Standard, including for any permitted health claims to facilitate clear messages for industry and consumers. For example it is noted that P1030's proposed definition for EDs, and permitted health claim in the draft variation refers to "sustained strenuous *physical activity*". However the permitted term allowed in the current Standard 2.9.4 for FSSFs is "sustained *strenuous exercise*." Consistent terminology should be used, as well as the term that most accurately describes *sporting activity* for which such products were designed to assist. Furthermore (if health claims continue to be permitted) "sustained

strenuous exercise" should be defined on the label and in associated product marketing.

2. Ensuring a mandatory advisory statement on all foods under Standard 2.9.4, including EDs

The draft variation does not appear to specify a mandatory statement for FSSFs and EDs "Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision". This statement exists in the current Standard 2.9.4 for FSSFs, and is recommended for a revised Standard 2.9.4. EDs are not necessary for most children or pregnant women, and should only be used under medical or dietetic supervision.

Frequent or excessive intake of EDs can substantially increase the risk for overweight or obesity in children and adolescents, and contribute to dental erosion.⁸ The 2007 Australian National Children's Nutrition and Physical Activity Survey found that 47% of children (2 to 16 years of age) consumed sugar-sweetened beverages (including sports drinks) daily.⁹ Mean daily intake for those children consuming sports drinks (2%) was large at approximately 620mL per day.¹⁰

3. Clear articulation of the specific target group in the health claim e.g. sports people

SA Health notes mandatory labelling information competes heavily with the marketing information on the labels of some sports products, which is likely to attract general consumers who don't exercise at the level intended for sports food or drink use. For example, Maximus Isotonic sports drink (1 litre bottle) is clearly targeted at young males (and hence would also be appealing to male adolescents) with product label messages such as:

- "Man sized Maximus" with an arrow at the top of the bottle to indicate the one litre bottle size, and "Wussy boy sized sports drinks" with an arrow around the (presume) 600ml bottle volume level;
- "So here's what you're gonna do. After you've slammed 1 litre stuffed with electrolytes into your body, sweated like a dog doing whatever man-like activity your were doing, crush this bottle in your gigantatron hand, check if anyone saw (they did and they're hot) and straight shoot the bin. Go hard, otherwise, what's the point?";
- On the NIP: "Serve size (man sized): 1 litre";
- Below the NIP: "Every ml of this bad boy contains 50% more electrolytes than the leading isotonic sports drinks".

The presence of such marketing messages on some of the EDs and FSSFs highlight the importance of adequate labelling of advisory statements and health claims that clearly define the correct target group for these products.

The overconsumption of discretionary foods (i.e. energy dense, nutrient poor foods) as a whole, and the contribution of sugar sweetened beverages such as soft drinks

and electrolyte drinks within this, is a significant national dietary issue in Australia. Sports drinks classify as a discretionary food.¹¹

The recent Australian Health Survey (2011-12)¹² found that 35% of total energy consumed by Australians (2 years and over) was from discretionary foods. The proportion of energy from discretionary foods was highest among the 14-18 year olds (41%). 51.2% of 14-18 year olds consumed soft drink and flavoured mineral waters, followed by 44.5% of 19-30 year olds, 36.4% of 9-13 year olds, and 34.9% of 31-50 year olds. Eight percent of 19-30 year olds consumed electrolyte, energy and fortified drinks, closely followed by 14-18 year olds (7.6%), 31-50 year olds (4.8%) and 9-13 year olds (1.7%). Too much dietary energy from discretionary foods and drinks displaces healthy foods from Australians' diets and contributes to overweight, obesity and tooth decay. In terms of water-based beverage volume sales, sports drinks are a growing category, showing 1% increase in volume share over 15 years (1997-2011) to reach 60 million litres and a per capita increase of 1.2L per person.¹³

4) If P1030 is progressed within its current scope, the current draft variation requires further revisions before being considered by the FSANZ Board for notification to the Forum

Given the issues highlighted thus far, the current draft variation requires further revisions. SA Health would like to see the next draft before it goes to the FSANZ Board for consideration and notification to the Forum. Furthermore, clarification is recommended regarding:

- Whether formulated beverages (currently defined in Standard 2.6.2- Non-alcoholic beverages and brewed soft drinks) will move across to Standard 2.9.4. As previously mentioned, there are a variety of EDs on the market that don't meet the proposed definition for EDs. For example, Gatorade Prime contains 21g of carbohydrate per 100ml, plus electrolytes and B vitamins. The current ED definition requires no less than 5g/100ml and no more than 10g/100ml of total sugars, and does not appear to include permissions for added vitamins and minerals. Hence this product appears to fit more with the current definition of a formulated beverage in Standard 2.6.2, but is clearly designed for sports people so could be considered for inclusion in a revised version of Standard 2.9.4.
- Some sports confectionery and sports gels contain electrolytes and caffeine. Caffeine and electrolytes do not appear to be currently permitted in FSFFs under 2.9.4.
- Does P1030 draft variation 2.1 under the Schedule provide additional, or a variation of, additive permissions for electrolyte drinks given Standard 1.3.1 operates as a hierarchy?

5) No indication on the current FSANZ work plan when a full review of 2.9.4 will take place

While P1030 is proposed as an interim arrangement pending the future review of Standard 2.9.4, SA Health is concerned that there is no indication on the current FSANZ work plan in relation to a full review. Given the issues outlined above, progression of P1030 is likely to result in a Standard that does not adequately

regulate the current variety of FSSFs and EDs on the market. SA Health would like to see a commitment to the full review of Standard 2.9.4 in the very near future.

Recommendations

SA Health:

1. Does *not* support progression of P1030 as it is currently drafted.
2. Recommends FSANZ instead commit to undertake a full review of Standard 2.9.4, including the possible capture of EDs, in the near future, in line with a previous FSANZ recommendation during the development of Standard 1.2.7 (P293). The scope of the review should:
 - reflect the wide variety of FSSF and ED products in the current market place;
 - consider if health claims should be permitted at all for FSSFs and EDs (including review of the international regulations and experience in this area); and
 - extensively review the evidence base for the wide array of FSSF and ED products now on the market, their safety and effectiveness in improving sports performance (guided by the AIS Sports Supplement Framework ABCD Classification system).
3. Recommends that, if the proposal continues in its current form, that it should not proceed to the Board until another consultation round (or at the very least a jurisdiction only consultation) is undertaken due to the complexity and number of issues needing further clarification and exploration. It is important that jurisdictions have opportunity to understand the issues raised, and to be comfortable that the revised drafting adequately captures the issues.
4. Recommends that any revision of Standard 2.9.4 must address adequate labelling on all FSSFs and EDs to ensure
 - mandatory advisory statements regarding unsuitability of use by children and pregnant women unless under medical or dietetic supervision; Should further health claims be permitted they must be clearly articulated, evidence based health claims identifying specific use only by sporting people for sustained strenuous exercise;
 - consistent use of terminology, and clear definitions for any permitted health claim terms in the revised standard (e.g. in relation to sustained strenuous exercise vs physical activity);
 - the definition of sustained strenuous exercise is included on the label near any permitted health claim.

References

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