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Tēnā koe

## Proposal P1030 – Consultation paper - Composition and Labelling of Electrolyte Drinks

Thank you for the opportunity to comment on this proposal. New Zealand Food Safety (NZFS) has the following comments to make.

### General comments

NZFS acknowledges the complexity of the task FSANZ has in reviewing the regulations for electrolyte drinks (EDs). While the clear intention of EDs is that they are designed for a particular sub-population, namely those participating in 60 minutes or more of strenuous physical activity, the reality is that these products are made available to and consumed by a much broader segment of the population. We appreciate the fine balance required to both strengthen the composition and labelling requirements for these products, to indicate both the intended purpose and the intended consumers of EDs more clearly, and to reduce the public health impact of these products on the general population.

Comments made in this submission focus on NZFS's strong preference that EDs are regulated as a special purpose food and that the requirements for EDs (that are updated as a result of P1030) are transferred to Standard 2.9.4 as part of P1010 Formulated Supplementary Sports Foods.

### Key points

- NZFS strongly suggests that the updated requirements for electrolyte drinks as a result of P1030 are transferred to Standard 2.9.4 as part of P1010. EDs are formulated to meet the needs of a specific type of consumer and as such align more closely with special purpose foods.
- NZFS are concerned about the nature of the evidence presented to substantiate the three general level health claims proposed. NZFS's view is that the level of evidence required should be equivalent to the level of evidence required for a food business to self-substantiate a general level health claim. That is, the evidence should be based on systematic reviews of the evidence for each food-health relationship claimed as per the requirements of Schedule 6, rather than being based on a literature review. We therefore recommend such evidence is required to underpin the three proposed health claims.
- NZFS has significant concerns relating to the prohibition of future self-substantiated claims on EDs. Hydration for sports performance is a rapidly evolving field of scientific research

and limiting future developments for claims in this area would significantly reduce opportunities for future innovation, potentially discouraging the use of the EDs Standard. The Standard would be much more adaptable to future scientific evidence if self-substantiated claims, with evidence to meet the requirements of Schedule 6, were to be permitted.

### **Proposed approach to regulation of Electrolyte Drinks – retaining in Standard 2.6.2 rather than moving to Standard 2.9.4**

Many of the requirements proposed in this consultation support the alignment of EDs with other special purpose foods such as:

- the prescribed name;
- the exemption from meeting the nutrition profiling scoring criteria (NPSC) to make health claims;
- the requirement for a statement outlining the intended use being linked to people undertaking at least 60 minutes of strenuous physical activity; and
- the exemption from declaring potassium in the NIP where a claim about sodium is made; etc.

NZFS supports this and strongly suggests that the updated requirements for EDs, as a result of P1030, are transferred to Standard 2.9.4 as part of P1010.

While it is our strong preference that EDs are regulated as special purpose foods (under 2.9.4 Formulated Supplementary Sports Foods), if it is not the intention of FSANZ to consider EDs under P1010 and rather it is the long term intention to regulate EDs as a general (i.e. not special purpose) food, then we suggest that the requirements, particularly around health and nutrient content claims, are aligned more closely with those of other general foods. This would include:

- listing the pre-approved General Level Health Claims in Schedule 4—5 along with the conditions for making the claims (composition and context statement etc);
- adding an exception to Standard 1.2.7-18(1)(a) to allow health claims on EDs that do not meet the NPSC;
- allowing future self-substantiated health claims; and
- allowing nutrient content claims to be made.

We make no further comment on the changes we believe necessary if the regulation of EDs as general-purpose food is to be the situation long term. The remainder of our submission focusses on NZFS's strong preference that EDs are regulated as a special purpose food and that the requirements for EDs that result from P1030 are transferred from Standard 2.6.2 to Standard 2.9.4 as part of P1010.

### **Definition of Electrolyte Drink**

NZFS supports FSANZ's proposal to remove reference to the replacement of carbohydrate from the definition of ED as a consequence of the proposal to lower the minimum carbohydrate content (see comments below). NZFS understands that the intended population group for these products (i.e. endurance athletes) are less likely to be using them a source of carbohydrate, because generally this is sourced from food/gels consumed together with a fluid/electrolyte mix. This practice is especially followed in hot climates where large amounts of fluid are required, and carbohydrate consumption is tightly controlled, though it is sport-dependent.

NZFS supports the removal of the words ‘represented as’ from the definition of an ED. The addition of the requirement that these drinks bear a prescribed name (see comments below) will help identify these drinks as EDs in a more definitive way.

## **Carbohydrate Level**

FSANZ states that the purpose of this review was to determine if lower carbohydrate (less than 5%) EDs have a similar effect on rehydration and exercise performance as those currently permitted in the Food Standards Code. The two parameters identified here are ‘rehydration’ and ‘exercise performance’. NZFS would like to know if these are the only two parameters considered in defining the requirements for food sold as an ED or ED base. Have other factors, such as level of hydration, sodium retention and perceived exertion related to the exercise performance been considered?

NZFS was unable to ascertain from the information provided in Supporting Document 1 whether the intervention products tested in the randomised controlled trials (contained in the literature review) compared directly, within the same trials, EDs that meet the current requirements (under section 2.6.2—9) with those that meet the newly proposed composition requirements for EDs. It is also unclear how ‘rapid’ was defined within the proposed definition because the trials contained in the review did not measure the speed of hydration in a way that could be compared. Speed of hydration is not only dependent on the total level of carbohydrate, but also the different types of carbohydrate present (each is actively transported by different receptors in the gut), the amount of electrolytes, the nature of the exercise, the temperature of the environment and the timing and amounts of intake.

While NZFS agrees in principle to the reduction in carbohydrate for public health reasons (to allow manufacturers to reduce the level of carbohydrate due to customer demand), the literature review provided in Supporting Document 1 (as outlined above) did not address the question of carbohydrate composition comprehensively enough. However, there is more evidence to support a reduction in the minimum level of carbohydrate from 5% to 2%, than there is evidence for maintaining the minimum at 5%.

## **Health Claims**

### **• Proposed permitted Health Claims**

The three proposed pre-approved general level health claims for electrolyte drinks relate to “rapid rehydration”, “rapid hydration”, and “contribution to the maintenance of performance by rapid hydration”.

These claims are supported by:

- a FSANZ literature search (completed in 2018 and repeated again to check for new publications in 2021); and
- a response to a health claims proposal by EFSA in 2011.

NZFS welcomes the proposal to add more pre-approved health claims in this area. However we understand that the evidence behind any proposed pre-approved claims is intended to be equivalent to the evidence companies are required to provide to meet Schedule 6 for self-substantiated claims. As a jurisdiction who regularly evaluates and enforces the requirements of Schedule 6 for self-substantiated claims, the evidence provided by FSANZ in this proposal would not meet this requirement.

NZFS also acknowledges that as this is a rapidly evolving area of scientific research, the evidence considered from EFSA is already ten years old and therefore may be quite outdated.

Therefore NZFS would expect that FSANZ would undertake systematic reviews for the proposed food health relationships that meet the requirements of Schedule 6, to underpin the proposed general level health claims. Such claims would need to include the dietary context statement described as the “proposed condition” in this proposal (ie, that such claims are relevant only to individuals undertaking strenuous physical activity for a time period of at least 60 minutes). NZFS would not support the inclusion of the pre-approved claims without this evidence.

- **Prohibition on other Health Claims**

NZFS does not support the suggested restriction on the scope of health claims to be made on EDs. We believe that this will unnecessarily restrict innovation in terms of future product/ ingredient development and the growth of scientific evidence regarding the application of EDs in sports performance. It is suggested that this restriction is removed. The requirements of Standard 1.2.7 will facilitate evidence based self-substantiated claims.

- **Removal of Current Therapeutic Claim**

NZFS supports the removal of the current therapeutic claim and replacement with others that are based on food health relationships substantiated via systematic reviews of the evidence.

- **NPSC**

NZFS considers that in the case of EDs, given their intended purpose for use by endurance athletes, it is not appropriate to meet the NPSC in order to allow a general level health claim requirement. These products are not intended for the general public (hence the importance of them being considered as part of P1010). NZFS acknowledges the “potential for non-target consumers to be misled by the requirement for and health benefits of such products in their own diets”, but the proposed claim condition that such claims are relevant only to individuals undertaking strenuous physical activity for a time period of at least 60 minutes, makes it clear to whom the claims apply.

- **Claim conditions**

***osmolality units and range:***

NZFS supports the FSANZ proposal to amend the units for osmolality to /kg for all compositional requirements.

***statement re 60 min strenuous exercise (context to health claims as well as determining intended purpose of product)***

NZFS supports the requirement for each of the pre-approved claims (should they be adequately supported by the appropriate level of evidence) to refer to the effects occurring under conditions of strenuous physical activity for a minimum time period of 60 minutes. We agree that this statement will help identify the intended target consumers for these products.

## Nutrient Content Claims

- **Removal of reference to minerals**

NZFS agrees that the reference to minerals from the definition and requirements for claims on EDs is removed.

- **Prescribed electrolytes**

NZFS notes that the claims “contains electrolytes” and “contains [specific electrolytes, e.g. sodium, potassium, calcium]” would both be acceptable on EDs. For greater clarity for consumers, we suggest that if the former “contains electrolytes” claim is made where the electrolytes are listed in the Nutrition Information Panel, they could be identified as electrolytes (e.g. Sodium (electrolyte)). This would also help in assessing compliance to the Standard for enforcement agencies.

- **Prohibition on other nutrient content claims**

NZFS assumes that the prohibition of other nutrient content claims is proposed because other nutrients are not permitted to be added to EDs. However, NZFS considers that nutrition content claims about energy and carbohydrates would also be very relevant for EDs, given the purpose they are designed for. For example, claims about the types and amounts of specific carbohydrate used are quite relevant to the speed of hydration, and would therefore be helpful for consumers. Therefore, we do not support a blanket prohibition on other nutrient content claims.

## Prescribed name

NZFS supports the requirement for ‘electrolyte drink’ to be a prescribed name. This will allow easy identification of EDs (and ED bases) which have been problematic for compliance purposes in the past. We note the prescribed name further reduces the need for the words ‘represented as’ from the definition of an ED (see further comments on definition above).

We consider the inclusion of a requirement for the prescribed name, being a new mandatory labelling requirement, would trigger the need for a WTO notification. We note that given many of these products use these words on pack currently, this should not cause an issue for imported EDs which are able to comply with the proposed amendments.

## Other areas

- **Caffeine**

Clarity is required on whether caffeine can be added to EDs. Currently it is clear from section 1.1.2—3 that formulated beverages are not permitted to contain caffeine. A similar prohibition is not provided for EDs, making it unclear as to whether or not caffeine can be added as an ingredient. MPI was involved in a High Court hearing regarding the legality of selling an isotonic sports drink containing caffeine. Although MPI and the Judge considered that caffeine could not be added to EDs, this case highlighted the lack of clarity for industry and government in terms of compliance with and enforcement standard 2.6.2. Based on this, NZFS seeks clarification in this Standard as to whether caffeine is permitted to be added as an ingredient to EDs or not. We appreciate that there could overlap here with P1056 Caffeine Review. We understand that the scope for P1056 will include permissions to add caffeine in sports foods. However, as EDs are not a special purpose food, we seek clarification from FSANZ on whether or not permissions to add caffeine in EDs or ED bases would be addressed in P1056. If EDs are not in

scope for P1056, we would request that EDs would be included in the scope and considered alongside other sports foods. This would mean that should EDs be transferred under Standard 2.9.4, there would be consistency in the way caffeine permissions are managed in sports foods.

- **Electrolyte claims on other foods**

NZFS notes that electrolyte claims on other foods is outside of the scope of P1030 however we wish to note that as a result, the ability for other beverages to make electrolyte claims and to be marketed in a way that may give consumers the impression that these are EDs remains. Notably, 'zero carbohydrate' drinks can still legitimately both contain electrolytes and make claims regarding their presence under the requirements of a formulated beverage and be eligible for making self-substantiated general level health claims. Placing requirements for making claims regarding electrolytes in Standard 1.2.7 rather than in 2.6.2 would allow compositional requirements for making claims regarding electrolytes to be added to Schedule 4 and would therefore apply across all foods.

NZFS notes that the proposed changes from the Consultation Paper contained in Attachment B is noted as an "example only". Can FSANZ please confirm if this 'example' is the draft variation proposed as part of this consultation, or will there be another round of consultation on the draft variation?

Nāku noa, nā

