

Proposal 1010

Formulated Supplementary Sports Foods – NSW Submission

Major Procedure – Consultation Paper One

Summary

NSW appreciates the opportunity to comment on Proposal 1010 (P1010) Formulated Supplementary Sports Foods – Consultation Paper One.

NSW concurs with FSANZ that Standard 2.9.4 (Formulated Supplementary Sports Food – FSSF) is no longer aligned with the range of products available to consumers sold as sports foods. Significant product and ingredient innovation has occurred since the inception of this standard into the Australia New Zealand Food Standards Code (the Code) with some of these innovations raising health and safety concerns.

NSW suggests that a comprehensive review of Standard 2.9.4 is required as there are differing risk profiles within the broad category of FSSF warranting consideration of a risk and tiered approach to regulation. There is further merit in considering appropriate warning and advisory statements on packages within these product tiers, commensurate with their corresponding risk. Risks imposed by over-consumption of specific high-risk ingredients (e.g. stimulant substances found in pre-workout, thermogenic and ‘fat-burner’ type products) pose an acute public health risk and should be regulated more strictly than simple amino acid supplements.

The definition of what properties a product possesses to be regulated by Standard 2.9.4 of the Code is also unclear. The difference between a specific nutritional goal and a specific performance goal in the definition of FSSF is not defined in the Code. This leads to ambiguity as to the functional purpose of stimulant substances when added as food ingredients in sport foods.

NSW suggests that clarifying these matters will create clear difference and segregation of FSSF from other Part 2.9 standards in the Code (e.g. Standard 2.9.3) to avoid the risk of a clearer Standard 2.9.4 creating an environment where a manufacturer amends product labelling (and not composition of substances of concern) to avoid tighter regulatory controls as a FSSF.

Close consultation and engagement will be required with the Therapeutic Goods Administration (TGA) as FSSF commonly raise food:medicine interface issues in their composition as well as their label and marketing statements.

NSW looks forward to further contributing to the review of Standard 2.9.4.

NSW offers further views on these issues as well as response to questions asked by FSANZ in the consultation paper.

Regulatory gap: substances added to FSSF (and other foods) for a performance-related purpose

The current definition of a FSSF includes language such as '*achieving performance goals*' and '*achieving nutritional goals*' of '*sports people*'. A relationship between 'nutritive substance' and attaining a '*specific nutritional goal*' of '*sports people*' may be inferred for the purpose of aligning the composition of FSSF with the FSSF definition. The same cannot be said for '*achieving performance goals*' of '*sports people*', this is a vague term that does not logically align with a defined functional purpose in the Code (e.g. nutritive substance, food additive, processing aid etc). Physiological effect in the context of '*achieving performance goals*' of '*sports people*' raises food:therapeutic goods interface issues. It may be prudent through Proposal 1010 to define the functional purpose associated with '*achieving performance goals*' to enable clear distinction between therapeutic use and a food-related purpose when added to FSSF.

This will greatly assist in assessing products that lie at the food:medicine interface. It will also give rise to a new type of substance that may be regulated through the express prohibition unless specifically permitted powers of Standard 1.1.1–10(5) and (6) of the Code. NSW considers the 'prohibit, unless expressly permitted' approach is appropriate for '*achieving performance goals*' type function of substances added to sports food as there are numerous substances added to FSSF for stimulant, thermogenic and fat-burning type functions that have health and safety concerns.

Substances such as dimethylamylamine (DMAA) and other analogues and methylxanthines (Dynamine) have been detected in FSSF. Both of these substances are no longer permitted to be added to FSSF as they are captured by Therapeutic Goods regulation, with some (DMAA, DMBA, DMHA) listed as Schedule 10 substances in the *Poisons Standard*¹. Recent product innovation in sports foods has revealed increasing use of 'English Walnut Extract' or '*Juglans regia*' (extract) in sports foods, investigation has revealed this to be a pseudonym for dimethylhexylamine (DMHA) – a Schedule 10 listed substance.

NSW raised similar concerns as to the function of caffeine when added to FSSF in its response to Proposal 1056 caffeine review as an ergogenic function was stated. NSW proposes that similar issues are evident for substances added to FSSF for '*achieving performance goals*' and suggests that regulatory clarity on the food-related function of these substances is necessary to ensure a level-playing field for domestic FSSF manufacturers (in competing with imports) as well as to innovators in the FSSF market so the line between food/therapeutic use is clear and unambiguous.

NSW considers current 'defined purpose' (e.g. nutritive substance) definitions in the Code may not be appropriate as they do not relate to the '*achieving performance goals*' purpose. Novel food permissions could possibly apply as they relate to non-traditional foods that require pre-market safety assessment. The only concern with the use of the novel food definition is current importation/availability of online product may result in challenge of the 'non-traditional' status of some of these substances. NSW considers pre-safety assessment should be applied to substances added to sports foods seeking to play a '*achieving performance goals*' purpose in FSSF, regardless of prior use to ensure independent safety assessment has been conducted on such substances prior to lawful use in FSSF.

The current FSANZ *Application Handbook*² requires '*information related to the nutritional impact or performance impact of the proposed compositional change*' that includes '*information on the performance goals of sports people, if it relates to the addition of a nutritive substance or novel food ingredient to foods regulated under Standard 2.9.4*'. Reference to the novel food

¹ <https://www.legislation.gov.au/Details/F2023L00067>

²

<https://www.foodstandards.gov.au/code/changes/Documents/FSANZ%20Application%20Handbook%201%20July%202019.pdf>

standard in the *Application Handbook* creates further distance between the ‘nutritive substance’ definition in the Code and an ‘achieving performance goals’ purpose in a FSSF, but the reverse is also not true – a novel food is not always added to food for a ‘achieving performance goal’ type purpose. The Code is silent on the purpose of addition of a novel food to a FSSF (or any other food). It only cannot be the same purpose as a defined term in the code (i.e. food additive, processing aid, nutritive substance). NSW suggests the regulatory identity of a substance added to FSSF for ‘achieving performance goals’ is clarified through Proposal 1010 so this purpose may be adequately separated from a nutritional or technological purpose. This will remove the possibility of substances claiming to have traditional use in the diets of Australia and New Zealand, and therefore including in FSSF without undergoing pre-market safety assessment.

NSW considers that this regulatory ambiguity has resulted in a ‘loophole’ that has enabled the addition of substances to FSSF for a performance-related purpose that have not been subject to pre-market safety assessment. This is a public health and safety issue as such substances do not have appropriately assessed safety profiles, and are pro-actively marketed at at-risk populations as purchase incentives. NSW provides an example below:

Example 1: Higenamine and Octopamine, are both listed on the World Anti-Doping Agency (WADA) prohibited list³. FSANZ’s imported food risk statements on higenamine⁴ and octopamine⁵ in supplementary sports foods recommend that these substances present a potential medium or high risk to public health. Nevertheless, the Code does not expressly prohibit the use of these substances in FSSF. The imported food risk statements further state in 2018 Higenamine was found in 10% of randomly selected ‘pre-workout’ or ‘fat burner’ supplements and Octopamine was found in 4%.

Noting the fast-growing and highly-adaptive sports foods industry, NSW supports the revision of FSSF to better define and manage risks associated with substances added for a performance-related purpose.

Definitions (Q2, Q4)

Definition of ‘FSSF’

NSW has identified the following issues resulting from the current definition of FSSF:

- The definition lacks clear description of its target population and purpose/function.
- The definition does not clearly distinguish itself from foods in other categories (general foods with sport representations, foods regulated by other Standards in Part 2.9 of the Code (e.g. formulated supplementary foods)) or therapeutic goods.
- The definition is not consistent with the *Policy Guideline on the intent of Part 2.9 – Special Purpose Foods*⁶ (see below)

Specific Policy Principles of the *Policy Guideline* require maintaining ‘a clear distinction between special purpose foods and other foods as regulated elsewhere in the Code’, in particular ‘Special purpose foods should be targeted only to those population groups satisfying the definition presented in the Scope/Aim section’.

The Scope/Aim section of the *Policy Guideline* states:

- ‘Part 2.9 – Special Purpose Foods, of the Code 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’

³ https://www.wada-ama.org/sites/default/files/2022-09/2023list_en_final_9_september_2022.pdf

⁴ <https://www.foodstandards.gov.au/consumer/importedfoods/Documents/Higenamine%20update.pdf>

⁵ <https://www.foodstandards.gov.au/consumer/importedfoods/Documents/sports-supps-octopamine.pdf>

⁶ <https://foodregulation.gov.au/internet/foodregulation.nsf/Content/publication-Policy-Guideline-on-Intent-of-Part-2-9-of-the-Food-Standards-Code-Special-Purpose-Foods>

- *'For the purposes of Part 2.9, 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.'*

To address these issues NSW suggests revision of the definition of FSSF to clarify:

- the target population, that is, 'sports people', what are they and how are they different to the general population?:
 - at or over 15 years of age (consistent with the existing warning statement), and
 - not pregnant (consistent with the existing warning statement) or lactating (proposed warning statement), and
 - engaging in physical activity at an appropriate intensity and frequency that requires altered energy intake (consistent with the *Policy Guideline*) acting under advice from appropriate qualified professionals (specifically excluding personal trainers).
- the purpose/function, that is,
 - a supplement to a normal diet to address situations where intakes of energy and nutrients may not be adequate to meet the altered dietary requirement influenced by physical activity *as the dominant purpose*, and
 - may also serve performance-related purpose, provided that ingredients added for this subsidiary purpose also serve a *nutritional purpose*.
- that FSSF excludes:
 - foods regulated by other Standards of the Code, and
 - therapeutic goods, in particular goods which satisfy the criteria for declaration that goods are therapeutic goods in accordance with the *Therapeutic Goods (Declared Goods) Order 2019*⁷.

NSW also suggests that consideration be given to what constitutes a '*sports person*' in the explanatory statement that accompanies any revision to Standard 2.9.4 as there is no current guidance provided as to how much physical activity a person needs to undertake and at what frequency to be considered a '*sports person*'.

New Definitions: 'high risk FSSF' and 'high-risk substance'

NSW suggests there is merit in exploring the tiered approach to FSSF provided by Q5. This would potentially envisage creation of a 'high-risk FSSF' and 'high-risk substance' with segregation of this category from standard FSSF. Determining the exclusive capture criterion for 'high-risk FSSF' would require careful consideration to ensure appropriate regulatory clarity.

Substances added for 'achieving performance goal' would be substances that could be most likely considered 'high-risk substance' with pre-workout and 'thermogenic' and fat-burning sports foods considered as 'high-risk FSSF'. Substances achieving this purpose generally have defined consumption thresholds and known toxic effects if consumed in excess.

Definition of 'one-day quantity'

NSW notes that currently the Code has the provision of 'one-day quantity' for FSSF in Standard 2.9.4 and formulated caffeinated beverages (FCB) in Standard 2.6.4, however, these two Standards provide separate definitions for 'one-day quantity' as follows:

- 'One-day quantity' for FSSF *'means the amount of that food which is to be consumed in one day in accordance with directions specified in the label'*.
- 'One-day quantity' for FCB *'is the maximum amount that should be consumed in a day'*.

⁷ <https://www.legislation.gov.au/Details/F2020C01051>

NSW considers it confusing to have two different definitions for the same term in the Code and proposes developing one definition of 'one-day quantity' that will be consistently applicable throughout the Code. NSW considers for 'high-risk FSSF' that the 'one-day quantity' definition in FCB is the more appropriate.

Furthermore, currently one-day quantity for each permitted substance is separately determined in Schedules 29–16, 18 and 19 (FSSF) and Schedule 28–2 (FCB) of the Code. As shown in the examples below, the one-day quantities for the same substance differs between the schedules:

- Thiamin: FCB 40 mg, FSSF 2.2 mg (RDI for general population 1.1mg – Sch 1)
- Riboflavin: FCB 20 mg, FSSF 3.4 mg (RDI for general population 1.7mg – Sch 1)
- Taurine: FCB 2000 mg, FSSF 60 mg

NSW understands the differing values for the same substance in FSSF and FCB for one-day quantity is due to the different approaches applied in determining these values, with FCBs being based on a lack of adverse effect, and with FSSF based on RDI values. This internal inconsistency in the Code creates confusion as to the meaning of 'one-day quantity' for consumers and will frustrate simple explanation to potential buyers of these products of the one-day quantity concept as FSSF and FCB are sold from the same retail outlets.

Proprietary blends (Q3)

NSW considers the current industry practice to list only the name of a proprietary blend in the NIP raises health and safety concerns as it does not appropriately convey essential information to enable consumers to make informed food choices on high-risk substances such as stimulants, thermogenics and fat-burners. Consumers should always be provided with the full list of all active ingredients in FSSF, including stimulants and other like substances in proprietary blends. This is needed to ensure appropriate consumption of such substances and to avoid unwitting over-consumption. NSW suggests that a revised Standard 2.9.4 of the Code require the listing of all active ingredients in FSSF in a prescriptive and numerical format, akin to all substances needing to be listed in the Nutrition Information Panel of any food that makes a voluntary claim. NSW notes advertising used in conjunction with these foods generally pro-actively markets the inclusion of such substances as a marketing point.

Stacking (Q3, Q8)

NSW considers that current regulation alone for one-day quantity (even using the FCB model) is not capable of appropriately managing safety concerns associated with voluntary intake of multiple serves of one-day quantity of FSSFs or blending of FSSF intake with FCBs, i.e. 'stacking' behaviours and 'stacking' marketing practices.

The required on-label information of a statement of the recommended consumption in one day (section 2.9.4—4), which is calculated in consideration of one-day quantity of a FSSF, does not prohibit 'stacking' practices and relevant advertisement. Recognising that high-risk FSSF can contain high-risk substances, NSW suggests the need for additional regulation against the promotion of multiple doses of high-risk substances from 'stacking' either from multiple doses of the same FSSF or from a mixture of FSSF and other foods that may contain such substances, such as FCB (see Q3, 8).

This may be best achieved by setting maximum one-day quantities of particular ingredients in the Code (from all dietary sources) and requiring foods that exceed 50% of this dose from a single serve to provide a mandatory advisory statement to inform consumers that exceedance of the one-day quantity of high-risk substances will result in negative health effects. An example may be found in the *Therapeutic Goods (Permissible Ingredients) Determination (No.*

1) 2023⁸ where requires the following warning statement applies '*Limit the use of caffeine-containing products (including tea and coffee) when taking this product.*', This applies to listed medicines for internal use or oral application with the maximum recommended daily dose containing more than 80 mg of total caffeine. NSW suggests there is merit in considering a similar approach on high-risk FSSF to require an additional warning statement to advise consumers to limit intake of products containing high-risk substances when consuming high-risk FSSF. The absence of such labelling advice to consumers may unwittingly promote over-consumption of high-risk substances.

NSW considers there may be merit in considering some form of regulatory control against 'stacking' practices to protect public health and safety, perhaps by reference to 'stacking' being a prohibited information requirement pertaining to the sale of FSSF and FCB (Standard 1.1.10-9), where one food contains 50% or greater of the recommended one-day quantity of the high-risk substance in question defined in Standard 2.9.4.

Tiered approach (Q5)

NSW notes that some ingredients in FSSF involve significant adverse effects when consumed by sensitive population or at large amounts. To better regulate such high-risk substances permitted to be added in FSSF, NSW would support a tiered approach to classify FSSF into two tiers, based on the risk of substances as ingredients:

- Low-risk FSSF: FSSF that does not contain high-risk substances
- High-risk FSSF: FSSF that contains high-risk substances

NSW would suggest:

- high-risk substances should be individually assessed and explicitly permitted in the Code with maximum one-day quantities defined for use in FSSF (when added as express ingredients). In all other instances use of such ingredients in other foods would be prohibited. Calculation of maximum one-day quantity would be based on all sources of the high-risk ingredient in the FSSF and would include natural sources.
- following the safety assessment, the listing of permitted high-risk substances in a Schedule should describe the conditions of permitted use, that may include:
 - the category(ies) of foods in which the use is permitted,
 - if applicable the threshold level (i.e. a substance would be regarded as high-risk if FSSF contains above a certain amount per serve)
 - the maximum permitted one-day level of the substance (to avoid over-consumption of such substances from all dietary sources). Advertisement for 'stacking' that may result in consumption of beyond this maximum limit should be prohibited (see Q3, 8).)
 - require warning/advisory statements that excess consumption of high-risk substances will result in negative health effects.
 - specific pre-approved health claims in line with the purpose of adding the substance in FSSF, provided that the FSSF also serves a nutritional purpose.
- restriction on sale should apply to high-risk FSSF (i.e. high-risk FSSF cannot be sold in supermarkets), and
- It should be an express offence to exceed the maximum permitted level for any defined high-risk substance.

NSW considers that substances with ergogenic and/or psychoactive property ('stimulants', 'thermogenic substances', 'fat burners') would be likely to be high-risk substances (see Q10).

Analogues and derivatives posing a health concern or risk (Q6)

⁸ https://www.legislation.gov.au/Details/F2023L00122/Html/Volume_2

NSW is aware that some products sold as FSSF contain analogues and/or derivatives of scheduled substances in the *Poison Standard* or substances listed in the WADA prohibited list, such as:

- English Walnut extract (pseudonym for DMHA– Sch 10 listed in the *Poison Standard*)
- Alpha GPC (pre-cursor to Acetyl Choline – Sch 4 listed in the *Poison Standard*)

These two substances are examples of why an explicit prohibition is required in the Code for the addition of such substances to products labelled as FSSF unless expressly permitted, as current practice for these products is referral to the TGA for regulatory action on the basis of use of listed medicines without appropriate permission. This is a resource draining management practice for both food regulators and TGA alike. An express 'prohibit, unless expressly permitted' offence in the Code would also assist in managing imports of such products as insurance companies will likely scrutinise the practices of importing businesses more diligently before offering insurance policies to importers of sports foods if there was an express offence in the Code.

Difficulties in compliance or enforcement (Q10)

Lack of the regulatory status of 'stimulants'

As previously identified in FSANZ's caffeine review⁹, currently the Code is silent about the regulatory status of substances added to foods for purposes other than 'a food additive', 'a processing aid', 'a novel food', or 'a nutritive substance', except for a limited number of substances directly regulated in the Code without classification (e.g. FOS/GOS, caffeine). NSW recognises that 'stimulants', 'thermogenics', 'fat burners' with ergogenic/psychoactive property, are added to some FSSF for a physiological and/or psychoactive purpose that is not a technological or nutritional purpose. A revised Standard 2.9.4 should address the potential health risk of 'stimulants', 'thermogenics', 'fat burners' through a similar prohibition unless expressly permitted requirement.

Caffeine, one of the commonly used 'stimulants', 'thermogenics', 'fat-burners' in FSSF, is currently individually regulated in subsection 1.1.1—10(5) with threshold limits set, however, taking the same approach for all other such high-risk substances would not likely be practical on an individual product basis. NSW contends that a new category needs to be created in the Code for such substances to be prohibited to be food for sale or used as an ingredient or a component of any other food for sale, unless expressly permitted. Explicitly permitted 'stimulants', 'thermogenics', 'fat-burners' or other like substances would be listed in a Schedule to the Code (likely Schedule 29) with detailed conditions of use, such as:

- types of foods that the substance may be added to,
- the maximum permitted one-day quantity that may be added to food for sale (including natural sources).
- Requiring mandatory advisory statements on any food containing 50% or more of the one-day quantity of each listed substance warning consumers that over-consumption of the listed substance will result in negative health effects.
- Prohibiting the use of 'stacking' advertising as an information requirement relevant to the food for sale, where the total of the 'stack' exceeds the maximum daily one-day quantity for the listed substance (see Q3, 8).),

Any 'stimulant' not on the list or not consistent with the permitted use, would need to be subject to pre-market safety assessment before being permitted to be added to foods. For more discussion see Q5.

Substances using different names

⁹

<https://www.foodstandards.gov.au/code/proposals/Documents/P1025%20Code%20revision%202CFS%20SD1%20Leg%20audit.pdf>

NSW recognises that some substances used in FSSF are listed in the NIP and/or ingredient list in various different names (e.g. 'extract/powder', Linnaean names). Examples include:

- Caffeine – 'Green tea extract', 'Green coffee bean', 'Matcha Green tea', 'Guarana', 'Yerba Mate', 'Kombucha', 'Kola nut', 'Cocoa'. '*Camilla sinesis* (tea)', '*Coffea arabica* (Coffee)', '*Coffea canephora* (Coffee)' and '*Paullinia cupana* (Guarana)'
- Synephrine – 'bitter orange'
- DMHA – 'English Walnut extract', '*Juglans regia*'

Sometimes the NIP and/or ingredient list of FSSF contain more than one name referring to the same substance. NSW views this situation as problematic as consumers would not be able to understand the amount of each substance in the product unless they know all the different names and understand the amount of active ingredient obtained from each source.

Products without identification

The current regulatory environment for sports foods/supplements is complicated because of the possible application of different regulations. Products sold as sports foods or supplements can be foods (FSSF or foods in other categories), therapeutic goods, supplemented foods or dietary supplements.

NSW is aware that some products with sports representation have no specific product category identification (i.e. no label identification as FSSF, listed medicine, supplemented food or dietary supplement). Such products fall to the food:medicine interface as they have ambiguous regulatory status.

As determined in Standard 1.2.2—2, 'formulated supplementary sports food' is a prescribed name and the prescribed name is required on the label of the food as its food product classification. Once a food has been assigned a prescribed name, it must clearly comply with all required elements of the named standard.

Currently the definition of FSSF is not specific enough to decide if a product should be FSSF based on its composition and marketing if it does not voluntarily declare itself to be FSSF. This creates a frustration for regulators as it requires the business to identify a product category before a compliance review may be initiated. NSW reiterates the suggestion for revising the definition of FSSF to appropriately define 'sport people', so that enforcement agencies have less ambiguity in food identification requirements (i.e. the duck test) for suspect product that is not voluntarily labelled as FSSF by the manufacturer.

NSW further notes the intent of the *New Zealand (Supplemented Food) Standard 2016*¹⁰ is to provide an interim regulatory arrangement for supplemented food until there are appropriate provisions in the Code. NSW would understand that the outcomes of P1010 (once gazetted) into the Code would result in review of corresponding provisions for sports foods and supplements in the NZ supplemented foods standard. NSW would appreciate some commentary on this matter as P1010 progresses.

Confusing listing of compositional limits

NSW finds that currently compositional limits for FSSF are not placed in the Code in a logical and organised manner. Namely,

¹⁰ <https://www.mpi.govt.nz/dmsdocument/11365-New-Zealand-Food-Supplemented-Food-Standard-2016>

- Potassium and sodium are listed in subsection 2.9.4—3(2), separately from all other minerals which are listed in S29—16. NSW suggests that the compositional limits for all minerals should be consolidated to one table in S29.
- L-carnitine, currently listed in S29—19 (Substances that may be used as nutritive substances in FSSF), should be listed in S29—18 (Amino acids that may be added to FSSF).

Reviewing the current listing would make the Code more user-friendly.

Placement of electrolyte drinks (Q11-13)

NSW supports regulating electrolyte drinks as FSSF under Standard 2.9.4. Considering similar roles of FSSF and electrolyte drinks, it is more logical to regulate electrolyte drinks as part of FSSF so all sports-related are captured by the same standard. There may also be merit in extending this approach to Standard 2.6.4 (FCBs) as these products are also generally targeted at sports people. Below further explains the positive impacts if electrolyte drinks are to be regulated under Standard 2.9.4.

Placement of electrolyte drinks in Part 2.9 is consistent with the Policy Guideline

The definition of electrolyte drink describes its purpose to serve the specific dietary requirement arising from physical activity: *'rapid replacement of fluid, carbohydrate and electrolytes during or after 60 minutes or more of sustained strenuous physical activity'*. This would satisfy the scope of special purpose foods (as it relates to sports foods) in accordance with the *Policy Guideline on the intent of Part 2.9 – Special Purpose Foods*.

Claims on the entire sports foods/drinks can be better managed under Standard 2.9.4

NSW notes that health claims on electrolyte drinks are prohibited other than three pre-approved claims that refer to effects occurring under conditions of strenuous physical activity for at least 60 minutes (subsection 2.6.2—16(2)). These claims reflect the purpose/role of electrolyte drinks, as described in the definition.

Considering the similar role that FSSF and electrolyte drinks serve, NSW considers that transferring electrolyte drinks to Standard 2.9.4 would allow for products targeting 'sports people' to be regulated by the same Standard.

NSW is aware that sports drinks, currently regulated under different standards (e.g. Standards 2.6.2, 2.6.4, 2.9.3, 2.9.4) of the Code, carry a variety of sport performance-related voluntary claims but have different compositional requirements (e.g. electrolyte drinks are required to have a minimum sugar content but 'zero sugar' sports drinks do not and both drink types contain substances labelled as 'electrolytes'). Permitted health claims on electrolyte drinks were reviewed through Proposal 1030, however, claims relating to 'zero sugar' sports drinks have not been reviewed to the same rigour, providing the situation where a business can sell 2 drinks under the same product name with differing claims permissions. The example is an electrolyte drink and a 'zero sugar' sport drink containing electrolytes. NSW encourages FSANZ to review this regulatory gap in this proposal and improve health claim regulations on the entire sports foods/drinks category. For further discussion about claims see Q19.

Improvement in consumer messaging

Placement of electrolyte drinks in Standard 2.9.4 would better inform consumers of the intended purpose of electrolyte drinks related to strenuous physical activity. In the Proposal 1030 Consultation Paper 2021¹¹, FSANZ identified that electrolyte drinks are consumed by non-target consumers including children and sedentary adults. However, no labelling

¹¹

<https://www.foodstandards.gov.au/code/proposals/Documents/P1030%20EDs%20Consultation%20Paper.pdf?csf=1&c=Q25uMs>

requirements have been developed to inform consumers of the purpose and target population of electrolyte drinks.

Given that both electrolyte drinks and FSSF have similar purpose and issue of consumption by non-target population, NSW considers it would be beneficial to include electrolyte drinks in FSSF under Standard 2.9.4 and require a statement on label about the role of FSSF, including the purpose/function and target population (as proposed in Q15).

Labelling requirements (Q14, Q16)

NSW supports retaining FSSF as a prescribed name. If a tiered approach is taken (see Q5), additional warning and advisory statements and compositional requirements would apply to high-risk FSSF to enable segregation from their low-risk counterparts.

Subsection 2.9.4—4(1)(b) requires the following information on label:

- directions stating the recommended amount and frequency of intake of the food; and
- a statement of the recommended consumption in one day; and
- a nutrition information panel.

While this set of required information ensures some instruction is provided on label as to how to use the product, it does not address ‘stacking’ behaviours. Stacking may lead to overconsumption of high-risk substances (such as ‘stimulants’) in FSSF, that may pose a health risk. To address this issue, NSW suggests:

- determining high-risk substances permitted for FSSF in the Code, with maximum permitted amounts
- Prohibition of advertisement for ‘stacking’ of products containing high-risk substances

For more discussion see Q3, 8.

NSW recognises that the NIP on FSSF can be confusing and misleading, by the use of the name of proprietary blends or Linnaean names. NSW suggests prescribing names of substances to be listed in the NIP in line with the name of permitted substances in the Code. For more discussion see Q10.

Furthermore, NSW suggests that all the required labelling information should also be available at the point of online sales, where consumers cannot view actual product labels. Taking into account rising online sales in the sports foods market in recent years, it is important to ensure a level playing field is maintained for consumer information for both online and retail store-based businesses.

Warning and advisory statements (Q15)

Subsection 2.9.4—4(1)(a) requires the following statements on label:

- a statement to the effect that the food is not a sole source of nutrition and should be consumed in conjunction with a nutritious diet; and
- a statement to the effect that the food should be used in conjunction with an appropriate physical training or exercise program; and
- the *warning statement ‘*Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision*’; and
- if the food contains added phenylalanine—the warning statement ‘*Phenylketonurics: Contains phenylalanine*’

NSW considers that the currently required advisory statements (the first two on the list above) do not clearly deliver a key message to consumers as to the role of the sports food as a special purpose food. NSW suggests replacing these two advisory statements with a statement clearly describing the purpose and target population, in line with the definition of FSSF. The description of the role of FSSF would sufficiently cover the points of the current advisory

statements (i.e. FSSF is a supplement to a normal diet, FSSF is for people engaging in physical activity). The required statement for formulated supplementary foods in subsection 2.9.3—6(4) may be of good reference.

NSW encourages FSANZ to conduct the risk assessment on FSSF intake by sensitive sub-populations in revising warning statements. NSW considers lactating women should be included in the warning statement, considering the potential risk to a breastfed infant through intake of substances specifically permitted in Standard 2.9.4. This suggestion is in addition to sub-populations already covered by existing warning/advisory statements applicable to sports foods.

Schedule 9—2 of the Code requires a mandatory advisory statement indicating that the food contains phenylalanine, if the food contains aspartame or aspartame-acesulphame salt. With a view to align with this statement, NSW suggests removing the term 'Phenylketonurics' from the existing warning statement on FSSF about phenylalanine as below, noting that 'phenylketonurics' is a medical term and not considered as plain English.

- ~~'Phenylketonurics: Contains phenylalanine'~~

Furthermore, additional warning/advisory statements should be required for FSSF containing high-risk substances. In a tiered approach, the additional warning/advisory statements should be incorporated in the labelling provisions for high-risk FSSF. For more discussion see Q5 and Q10.

In relation to the requirements in Standard 1.2.1, as mentioned in the Consultation Paper (pg23), NSW suggests required labelling information in section 2.9.4—4 may be declared by any other means for low-risk FSSF. However, NSW recommends high-risk FSSF should not be sold without appropriate labelling on the package. This means high-risk FSSF can only be sold in a package. NSW believes this limitation on high-risk FSSF is justified considering the high-risk nature of these products, warranting the clear provision of appropriate warning/advisory statements for consumer health and safety.

NSW also suggests that all the required warning and advisory statements should be provided at the point of online sales, where consumers cannot view actual product labels.

Usefulness of the labelling statements in Division 3 for particular sports foods (high carbohydrate supplement, protein energy supplement, energy supplement) (Q17)

NSW considers the provisions in Division 3 are not useful. Many products that may be applicable (e.g. energy bars) are sold as general foods with sports representation and consequently exempt from the requirements.

NSW notes that optional statements in Division 3 have a similar nature to health claims. NSW suggests incorporating the components into permitted health claims for FSSF.

Claims (Q19)

NSW notes that claims about physiological effects, such as gaining muscle; increasing mental focus; increasing metabolism; increasing stamina; increasing testosterone levels; reducing oestrogen levels or otherwise modifying hormone levels; losing weight or fat; preparing for workout; recovering from workout, reside in the *Therapeutic Goods (Declared Goods) Order 2019*⁷. Section 1.2.7—8 explicitly prohibits claims from being therapeutic.

This narrow area for permissible claims provides an opportunity to consider an approach to voluntary claims on sports foods that is similar to that applied to electrolyte drinks through Proposal 1030. This is to permit a small range of pre-approved claims but not permit self-substantiation.

ENDS

The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.

Dated as 16 March 2023