# P1010 – Review of Formulated Supplementary Sports Foods

## Call for data on substances used in contemporary sports foods

### SUBMITTER GUIDANCE

**Scope of the P1010 Call for Data**

Food Standards Australia New Zealand (FSANZ) is currently reviewing Standard 2.9.4 – Formulated Supplementary Sports Foods of the Australia New Zealand Food Standards Code (the Code).

FSANZ is conducting a *Call for Data* on substances for use in formulated supplementary sports foods (sports foods) as part of the review.

Any changes to the compositional requirements for substances added to sports foods must be assessed by FSANZ in accordance with the *Food Standards Australia New Zealand Act 1991* (the Act). The Act requires that any amendment to the compositional requirements of sports foods must be first considered as warranted by FSANZ, using an evidence-based scientific assessment and having regard to each of the criteria listed in sections 18 and 59 of the Act.

FSANZ is calling upon interested parties to provide the necessary supporting information on substances that may be suitable as ingredients in sports foods. Substances of interest may be new to sports foods in Australia and New Zealand (e.g. citrulline, ashwagandha, betaine), or covered by existing permissions but at different quantities (e.g. amino acids). Information is sought addressing the following areas:

- Technical data and manufacturing processes
- Proposed usage
- Safety
- Dietary exposure
- Function and Benefit
- Any additional supporting literature, published or unpublished, that can inform risk assessment.

More detail on the type and quality of information required by FSANZ is provided in the *Explanatory Notes* below.

**Out of scope for this Call for Data**

Please note that at this time FSANZ is not seeking opinion on the value and legitimacy of each substance being evaluated for inclusion in sports foods. Two periods of public consultation on the assessment of Standard 2.9.4 will occur at a later date.

FSANZ is seeking to update general permissions relating to the composition of sports foods. Do not nominate a substance for inclusion in sports foods in this Call for Data process if you want an exclusive permission for that substance. FSANZ's usual procedures for seeking

changes to the Code can still be engaged by an applicant while this review is underway, and following gazettal.

Material relating to 'electrolyte drinks' is excluded from this Call for Data as these products are regulated under Standard 2.6.2 and have recently been considered under Proposal P1030.

Consideration given towards permitting additional substances as ingredients in sports foods as part of this review will be submitter driven and rely heavily on the appropriate information being provided to FSANZ as outlined in this Call for Data.

### How FSANZ will use the information provided

FSANZ will independently evaluate the supplied information to determine if suitable evidence exists to justify amending the Code to change the compositional requirements of sports foods. In doing so, FSANZ will have regard to the benchmark set by relevant data and information requirements set out in Part 3 of the Application Handbook.

The Australian Government's Information Publication Scheme and the provisions of the FSANZ Act aim to promote transparency and pro-disclosure to inform and facilitate public participation in decision-making. FSANZ consults publicly on all applications and proposals to change the Code and welcomes feedback from the community. With the exception of any confidential material, FSANZ intends to summarise the submitted information supporting a new or changed substance permission in Standard 2.9.4. These summaries are for publication on our website and will be to a level of detail consistent with international best practice and FSANZ policy of transparency.

### Protection of confidential data

Under our legislation, FSANZ is required to treat information as confidential if it identifies trade secrets relating to food and any other information relating to food, where the commercial value would be or could reasonably be expected to be destroyed or diminished by disclosure. FSANZ will not disclose or publish information identified as confidential.

*Confidential information must be clearly identified and separated in any submission made to FSANZ as part of this Call for Data.* An explanation of why submitted information is considered confidential must be provided. Submitters that have provided confidential information used by FSANZ to support inclusion of an additional substance into sports foods will have the opportunity to review FSANZ documentation for confidential information prior to public release.

# EXPLANATORY NOTES

## General Requirements

All information submitted to FSANZ must be in English, or be accompanied by a full English translation. It must consist of full electronic copies. Abstracts or summaries alone are unsuitable for assessment.

A submitter should carry out a literature search in the process of collecting scientific information to support this Call for Data, providing the details of the search strategy and subsequent results (what was done, why, and what was found). This will allow FSANZ to determine if a complete and balanced representation of available evidence has been made available before undertaking an assessment.

### *1) Technical data and manufacturing processes*

For new substances being nominated, detailed chemical and physical properties must be known by FSANZ, to allow specification in relevant standards.

For single chemical entities this includes information like chemical name (according to both Chemical Abstracts (CA) and the International Union for Pure and Applied Chemistry (IUPAC)); structural formula; common name and synonyms; manufacturers' code; marketing name; and CAS registry number. For biologically-derived substances, the source must be known down to the species level or, where relevant, subspecies/strain.

For substances that are not distinct chemical entities, a name should be specified that describes the substance as completely as possible. The sources of the substance should be provided, together with either sufficient compositional data to accurately identify the substance, or reference to its common name in other publications used by regulatory agencies. For substances that are derived from animals, plants or microorganisms, the source should be provided.

For the purpose of enforcing limits that may be prescribed in the Code, a robust analytical method suitable for regulatory laboratories to detect and quantify the substance or its degradation products must be known by FSANZ. Further, studies on the stability of the substance, in particular detailing losses during processing and storage to the end of shelf life, must be known for all relevant food groups, individual foods or food matrices.

FSANZ must establish a detailed understanding of the methodology used to manufacture, synthesise or extract a substance, to assess the likelihood of food safety issues arising during substance preparation. This information includes an understanding of all impurities, including isomers and manufacturing by-products, and recognising any methods employed for reducing anti-nutrients or naturally-occurring toxins during processing. Where possible, impurities should be identified by their CA or IUPAC names.

### *2) Proposed usage*

FSANZ must know the purpose of any substance under consideration for inclusion in sports foods. This includes all technological, nutritive or health-related function of the substance, at the proposed levels in foods and considering the target population. Any population sub-groups that should be excluded from consuming a substance under assessment need to be clearly identified. Where an added substance has multiple purposes or functions, these also need to be identified.

Without a clear understanding of the proposed usage of a substance, FSANZ cannot undertake an effective safety, benefit, and dietary exposure assessment.

### *3) Safety*

Detailed information concerning safety of a substance is essential before FSANZ can permit any additional ingredients into sports foods.

FSANZ requires this information to establish whether a health-based guidance value (HBGV) such as an acceptable daily intake (ADI) needs to be specified, and to possess sufficient information to establish these values if required.

Studies that are important to FSANZ to address substance safety include the following:

a. Metabolism and pharmaco- or toxicokinetic studies.

b. Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals.

c. Genotoxicity studies.

d. Special studies designed to investigate specific effects, such as the mechanism of toxicity, immune responses or macromolecular binding.

e. Information regarding the potential allergenicity, which may include reports of allergenicity associated with the substance.

f. Studies in humans if available.

FSANZ prefers studies that are designed and conducted in accordance with OECD Principles on Good Laboratory Practice and relevant OECD guidelines for the testing of chemicals, or other recognised test guidelines. All studies conducted for a regulatory purpose and reviewed by FSANZ should be accompanied by evidence of a quality control/assurance program or evidence of independent auditing of the conduct and reporting of the study. Studies should contain full details of the conduct of the study and its results, including raw data where appropriate.

Details on current consumption of a substance in population sub-groups or in other countries can be important for establishing safety and should be provided if available. This includes information on the extent and history of use; any particular preparation, processing or cooking practices normally used; the frequency of consumption; and the level and purpose of consumption (e.g. staple food, ceremonial use).

If the substance under consideration is used in dietary supplements, natural medicines or complementary medicines, FSANZ must review the relevant safety evidence of substances in these products. In some countries, this is regarded as food use rather than medicinal use. If adverse events are reported for nominated substance, regardless of the type of use, the nature of the adverse event reporting scheme needs to be understood.

In cases where particle size is important to achieving the nutritive purpose of a substance, or may relate to a difference in nutritional status or toxicity, FSANZ must assess information on particle size, size distribution, and morphology, as well as any size-dependent properties. Therefore, submitters should provide relevant information in relation to this aspect.

Where a substance interacts with other relevant substances included in sports foods, this must be identified and discussed.

### *4) Dietary exposure*

Detailed information concerning the dietary exposure of consumers to a substance and how its introduction into the marketplace may alter the diet of the population is essential before FSANZ can permit any additional substances into sports foods.

FSANZ must consider a detailed list of the foods where a substance will be used, along with information about the nutrient content of the food (e.g. energy, total fat, saturated fat, total sugars, sodium). Additionally, concentration data for the substance must be provided by the

submitter. This must include a proposed maximum level of use for a substance in each food group or food, typical levels of use if available, and include information about the naturally-occurring levels already present in foods.

The consumption amounts of sports foods also need to be used in the dietary exposure assessment and data distinguishing likely consumption levels among target and non-target groups are preferred. Submitters should provide any information available on recommended consumption amounts (e.g. product label information) or recorded consumption amounts from consumers. This should also include demographic information for the target group and/or evidence of who is consuming sports foods.

Estimates of dietary exposure to the substances from sports foods should submitted for consideration by FSANZ in the assessment, as can estimates of dietary exposure from all sources (e.g. naturally occurring and added). Information from other countries can be submitted.

FSANZ must understand the percentage of the market likely to use an additional substance if permitted for use in sports foods. This must account for projected uptake of the use of a substance in foods or market share data for foods where use of the substance is likely, and incorporate evidence demonstrating that the consumption of food(s) containing a substance does not pose adverse risk in any population sub-groups (e.g. particular age or cultural groups).

### *5) Nutritionally-related beneficial or adverse effects*

FSANZ must assess all relevant scientific evidence to determine whether the substance under consideration has any beneficial and adverse nutritional effects. Beneficial effects may include the achievement of specific, meaningful sports performance goals using valid methods and outcomes. Adverse effects must be investigated and must include nutritional imbalance, negative public health impact, unfavourable sports performance, and any other identified nutritionally-related adverse effect, using valid methods and outcomes.

Submitters are asked to provide all relevant scientific evidence in the form of published or unpublished reports and any associated supplementary material. The evidence must allow for the proposed beneficial effect and adverse effects (or lack thereof) to be attributed to the substance under consideration. Ideally, the scientific evidence supporting nutrition impact should be based on human subjects, relate to normal consumer use, and the substance or containing sports food must contribute to the demonstrated nutritional role relevant to that consumer.

Sufficient information also needs to be available for FSANZ to determine the amount of the substance in food groups or foods that is necessary to achieve the nutrition or health related benefit. Information about the likely dietary intake by consumers must also be understood.

### *6) Additional supporting Information*

Any additional information not described in the sections above that will assist FSANZ in determining the suitability of a substance as an ingredient in sports foods should also be submitted.

FSANZ may also contact submitters to the Call for Data directly to clarify or seek further information.