Proposal P1024
Revision of the Regulation of Nutritive Substances & Novel Foods

Major Procedure

Submission

The NSW Food Authority (Food Authority) recognises the key role of the novel food standard and nutritive substances in permitting legitimate food industry innovation, whilst maintaining consumer health and safety.

The Food Authority agrees that legal ambiguity associated with current definitions in the novel foods standard (Standard 1.5.1 of the Australia New Zealand Food Standards Code – the Code) and nutritive substances is limiting the effectiveness of these standards in achieving their intended purpose. Key examples are 'normally consumed' and 'nutritional purpose' with regard to nutritive substances and 'history of human consumption' with regard to novel foods.

The Food Authority argues this ambiguity is not resolved by the changes to the language in the Code through the Proposal 1025 process, whereby the definition for "nutritive substance" was changed to "used as a nutritive substance" in an endeavour to provide greater clarity.

In terms of perception, there may be a view that the definition "used as a nutritive substance", in the form of an operative phrase, is more confusing, rather than less, compared to the previous term, "nutritive substance".

The Food Authority also notes that further attempts to define the ambiguous terms within the existing definitions with either sub-definitions, clarifying statements or expanded meanings adds to uncertainty.

Currently this ambiguity is driving regulators to rely on unsafe and unsuitable provisions in state Food Acts as a regulatory measure to manage innovative foods/food ingredients until such time as sufficient information may be obtained with regard to safety (microbiological, chemical), suitability and nutritional quality/efficacy in the human diet.

The Food Authority is supportive of considering alternatives to the status quo and sees merit in further developing a risk based approach so that regulatory scrutiny is aligned with plausible risk to human health and safety.

The Food Authority is concerned that the proposed 'eligible food criteria' concept will be difficult to clearly legislate in the Code and therefore difficult to practically enforce.

Draft wording for Code amendments for ‘eligible food criteria’ is not provided at this time, so comment is provided on the concept itself and where it may best fit.

The Food Authority has further concern with regard to compliance of the ‘eligible food criteria’ concept with regard to specific policy principle (e) in the Ministerial Policy Guideline for the fortification of substances other than vitamins and minerals, in the event that dossiers permit marketing of nutritive substances and novel foods prior to regulatory scrutiny. This principle requires that the presence of a fortificant substance should not mislead the consumer as to the nutritional quality of the food. It is not clear to the Food Authority how compliance with this policy principle would be achieved in a market environment where new substances may be marketed as food without pre-market regulatory scrutiny.

As an alternative, the Food Authority requests that FSANZ explore the possibility of further developing and adding ‘eligible food criteria’ to the application handbook as it usefully provides a framework for substances requiring pre-market safety assessments. In the current context this applies to nutritive substances and novel foods but may also extend to food additives and processing aids in the future.

The key benefit provided is the ability to allow risk assessments to recognise work conducted by international authorities (e.g. JECFA, FDA) so applicants may compile their own safety assessments (in accordance with clear direction as to content) and provide to FSANZ for review. Depending on the breadth of information provided in the assessment, FSANZ may only be required to undertake a dietary exposure assessment to determine issues such as contribution to total dietary intake, any anti-nutritional factors prior to providing approval to a substance as a novel food or nutritive substance.

This approach may likely entail developing a set of guidelines developed under the Code to inform on the risk assessment process and what information is required.

This will enable FSANZ resources to be effectively deployed where there is a clear information gap with regard to safety issues and dietary exposure assessments.

The Food Authority is not supportive of self substantiation as a pathway for safety and dietary exposure assessments for novel foods and nutritive substances as it considers this will run a significant risk of nationally inconsistent outcomes. There may be a perception in these circumstances that FSANZ is not acting consistently with the objectives of its role in preparing and reviewing food regulatory measures.

Further, there is significant concern about the capacity of jurisdictions to resource such a process as all dossiers would need to be reviewed as a priority as they consider health and safety issues, and may also raise issues concerning the clarity of substances as foods or therapeutic goods.

Industry self-assessment dossiers concerning health and safety issues is a fundamentally different proposition to self-substantiation of food:health relationships in general level health claims. In the instance of health claims, the status of substances which the claim may be applied as a food is clear, as is the toxicology of foods to which the claim may be applied (microbiological and chemical) and the metabolism of these foods in the human body. All of these issues would need to be reviewed by jurisdictions under a self substantiation approach, creating a risk of inconsistent outcomes.

A centralised assessment process conducted by FSANZ addresses this risk whilst maintaining the traditional distinction between the role of FSANZ as a bi-national standards setter and state/territory jurisdictions as compliance and enforcement agencies.

This alternative approach would also envisage retention of the nutritive substances definition and novel foods standard in the Code. The Food Authority considers retention of these standards important as they serve a clear purpose in providing pre-market safety assessment requirements prior to legal supply as a food.

As part of this suggested alternative, it may be necessary to amend the novel food standard and nutritive substances definition to ensure that processes outlined in the applications handbook are followed in seeking to permit a novel food to enter the marketplace or seek to have a substance declared a nutritive substance.

Given that Standard 1.2.7 already provides the ability for self substantiated general level health claims to occur, it is essential that the regulatory framework governing the ability of substances to declare themselves to be of a particular status (e.g. nutritive substance) or a food (novel food) requires pre-market regulatory scrutiny.

To enable the 'eligible food criteria' concept and the proposed pathway to move forward, the Food Authority suggests that further work and clarity is required on the following issues:

- The outcome of a food/food ingredient with regard to an assessment pathway should it not qualify for 'eligible food criteria'. The Food Authority would prefer that FSANZ pre-market assessment become the default approach in all instances where potential foods/food ingredients do not qualify as 'eligible food criteria'.
- The definition of 'pharmocological properties' and how this will influence the assessment pathway of a potential food/food ingredient, in particular for ingredients in complimentary medicines and dietary supplements that are at the food-medicine interface. The role of FSANZ and the TGA in the regulatory management of these products can be unclear.
- How 'potential for adverse effects' will be qualified as a means to require pre-market assessment?
- Further definition surrounding the application of 'gateway tests'.
- Business awareness and understanding of processes in the FSANZ application handbook so the expected rigidity and content of assessments is clear. This is particularly important given information provided in Supporting Document 2 surrounding risk assessment. For example, diet history will need to span 3 generations in order to satisfy toxicological safety, clear and unambiguous definition of taxonomic unit with regard to microorganisms will be required to establish microbiological safety, and establishment of possible anti-nutritional factors in the diet will need to occur to establish nutritional safety.
- Recognition of international authorities in conducting risk assessments (e.g. JECFA, EFSA, FDA).

With regard to the eligible food criteria itself, clarity is sought on interpretation of the following matters:

- Eligible food criteria 1: how will genetic stability be defined and measured? The Food Authority further notes that the parallel example of the Qualified Presumption of Safety (QPS) in the EU only applies if the microorganism is to be used in accordance with the basis for its listing in the QPS and any other conditions are met. This is a further issue to consider in the development of this work.
- Eligible food criteria 2: Will the Code exclusively define the exclusion of fungi and algae and any other whole foods (e.g. ackee fruit) from the list of whole foods that may be considered eligible? If so will this result in pre-market safety assessment by FSANZ prior to legal supply? What is physical fractionation and where does it apply?
- Eligible criteria 4: how will 'natural range' be defined and applied? Supporting Document 3 provides some guidance but is not explicitly clear.
- NSW agrees that the terms "reasonable potential" and "reasonably expected" are ambiguous and would need to be clearly defined.

Should the eligible food criteria be sufficiently clarified with the options and pathways made clear, the previous role of the Advisory Committee for Novel Foods is addressed as the ambiguity of process with regards to what is required of a substance requiring pre-market safety assessment is removed.

A further alternative option may be to further develop 'eligible food criteria' as a guideline under Section 13 (1) (c) of the Australia New Zealand Food Standards Code to aid in the interpretation of the novel foods standards and the nutritive substances definition. This could then be used by regulators, through the Advisory Committee for Novel Foods (ACNF), as a guide to facilitate the process of regulatory scrutiny of substances requiring pre-market safety assessment. This option is not preferred as it does not address the legal informality of decisions made by the ACNF, nor the failure of the novel foods standard and nutritive substance definition in managing substances that require pre-market safety assessment.

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.