

Proposal P1024

Revision of the Regulation of Nutritive Substances & Novel Foods

Major Procedure - Consultation paper June 2017

Submission

Proposal for two assessment pathways (including 'eligible food criteria')

The NSW Department of Primary Industries, which incorporates the NSW Food Authority, and NSW Health (NSW) acknowledge work undertaken by FSANZ to address divergent stakeholder positions provided through the first call for submissions to develop the modified framework proposed in the consultation paper.

NSW understands the current proposal to include two assessment pathways, a pathway governed by 'eligible food criteria', where innovation would be permitted without pre-market safety assessment by FSANZ and a pathway that would require pre-market safety assessment by FSANZ (essentially status quo).

In the absence of clear detail on the nature of 'eligible food criteria' in the consultation paper, NSW is not able to provide a position on the proposed 2 pathways.

NSW provides 'in-principle' support for FSANZ continuing to explore development of the two-assessment pathways proposed. NSW offers some specific comment on the nature of 'eligible food criteria' to ensure the desired outcome of certainty for all stakeholders is achieved:

- The description of 'Eligible food criteria' must be clear and unambiguous, in both the drafting in the Food Standards Code (the Code) and its subsequent interpretation. There is a very high likelihood of national inconsistency should such clarity not be provided.
- Clarity in interpretation of the Code for fundamental matters such as whether something is a food is not a matter for referral to the Implementation Sub-Committee for Food Regulation. Proposal 1024, is primarily concerned with food industry innovation for a nutritional purpose. NSW considers that ambiguity should not be introduced on the classification of a substance as food or whether that substance is safe.
- Food industry innovations for a nutritional purpose are also very likely to attract claims surrounding health benefits. NSW notes the existing framework for *Standard 1.2.7 – Nutrition, health and related claims* provides an existing model for self-substantiation of general level health claims. However, under

the current approach, the safety of the substance to which the claim is applied is not in dispute, nor is its status as food. Ambiguity in either of these areas is not desirable.

- 'Eligible food' should not create conflict for the classification of something as food given the *Ministerial Policy Guideline for the Addition to Food of Substances Other than Vitamins and Minerals* specifies that consumers must not be misled as to the nutritional quality of food by added substances. In a market where 'new' foods may be marketed without pre-market approval (i.e. they are 'eligible food'), ambiguity as to the status of something as 'eligible food' should be avoided.
- 'Eligible food criteria' should be supported in the Code with at least two offence provisions. One should concern a prohibition against sale and supply for something determined not to be 'eligible food' until pre-market safety assessment has been conducted by FSANZ, and the other should concern sale and supply of something considered to be 'eligible food' if all matters stated in the Code concerning compliance with 'eligible food criteria' have not been met.
- Requirements for evidence keeping to support claimed status as 'eligible food criteria' should be detailed in the Code as 'must' requirements. This should provide for application of the offence provision described above concerning sale and supply of 'eligible food' in compliance with all relevant requirements of the Code.
- NSW notes that the cost of reviewing data held by food businesses (to support the safety of 'eligible food') will need to be recovered from Industry. In NSW, reviewing this data would be an inspection of non-licensed food business, the cost of which in 2017 is \$322 p/h under Food Regulation 2015.

NSW also notes learnings from this process should inform review of food additive and processing aid standards. There may be some merit in considering whether it is more desirable from a Code effectiveness perspective to review all these standards at the same time as all are 'regulated substances' (requiring pre-market safety assessment). Currently it is the intended end use that determines which food standard applies.

Deletion of Schedule 25 from the Food Standards Code

NSW is concerned that deleting Schedule 25 from the Code will result in substances that have had pre-market safety assessment and their status as foods established losing definitional clarity and certainty. NSW agrees there is merit in exploring an appropriate timeline for duration of novelty but considers there is risk associated with complete deletion of assessed and approved substances from the Code. NSW suggests that an alternative could be to classify them in the new list that will need to be created to account for pre-market safety assessment outcomes required for foods determined to not meet 'eligible food criteria'. The title of this list is a matter for FSANZ to determine but NSW would understand that this list would perform the same function as that of Schedule 25 currently.

Deletion of used as a nutritive substance

NSW does not support deletion of the term 'used as a nutritive substance' from the Code. NSW considers that the term 'nutritive substance' should be retained as it refers to a broad range of substances added to food for the purposes of making claims. These claims are made for product differentiation and marketing purposes and includes substances such as nucleotides, choline, creatine, inosine, inositol, lutein, ubiquinones, gamma oryzanol and taurine in addition to vitamins, minerals, electrolytes and L-amino acids.

The addition of these substances to food for a nutritional purpose (to support a health claim) should be supported by assessment to ensure that consumers are not misled.

NSW also cites compliance with the Policy Guideline for Addition to Food of Substances other than Vitamins and Minerals as a matter for further consideration in the development of Proposal 1024. Within this Guideline is specific policy principle (e) that requires the presence of the added substance to not mislead a consumer as to the nutritional quality of a food. In a market where 'new' foods may be marketed without pre-market approval, there should not be ambiguity as to the status of something as 'eligible food' nor ambiguity as to the evidence keeping requirement of a party proposing to make a claim in relation to that substance.

Amended data requirements for applications

NSW supports FSANZ exploring methods for streamlining assessment processes through modification of the applications handbook, provided the same certainty of outcome is achieved.

Exclusivity

NSW suggests that Industry should instead pursue avenues for intellectual property (IP) protection with the Commonwealth through IP Australia. NSW understands that industry can pursue patents on technologies used to produce a substance that is novel or patents on a novel substance. NSW further understands that patents offer 25 years' market exclusivity. Successful innovators may be better served by patenting their inventions and on-selling the ability to use the patents to third parties in exchange for royalties. Such a system would provide a long-standing benefit to innovators and provide clear avenues for referral of infringements.

Grandfathering

NSW is concerned that the proposed 'grandfathering' concept may result in conflict regarding obligations to prevent the sale of unsafe and unsuitable food in NSW. The Code establishes a legal framework to facilitate the production and trade of food. State and territory food enforcement agencies are established to prevent the sale and supply of unsafe and unsuitable food, prevent misleading conduct in relation to the sale of food and to provide for the application of the Code in a state or territory.

A state and territory food enforcement agency is obliged to observe the objects of its enabling Act when a matter is referred to it for consideration, or it discovers a matter through pro-active monitoring and surveillance. The time of original supply of a food is irrelevant to this consideration. If an alleged offence is substantiated, the enforcement agency, by the objects of its enabling Act is obliged to take appropriate action.

NSW considers that the primary responsibility for ensuring that food is safe and suitable lies with Industry. If Industry is unclear about the safety or suitability of a substance as food at a given point in time, it is encouraged to take pro-active action to remedy this.

Neither FSANZ or jurisdictions can identify all foods available on the market at any point in time and as such cannot ensure that all nutritive substances and novel foods have undergone pre-market safety assessment. NSW understands the 'grandfathered' approach would permit nutritive substances and novel foods that are 'on the Australian and New Zealand markets at the time of gazettal' (how 'market' is demonstrated is undefined) to be permitted to be sold without having to comply with either the revised standard or the current standard. NSW will enforce the Code, and the objects of its enabling Act at the point in time a matter is referred for consideration.

Change management in food standards and the content of food standards is a matter for FSANZ to manage through transitional arrangements.

Microorganisms

NSW is not supportive of 'grandfathering' all foods produced with live food culture microorganisms for the same reasons as provided above.

NSW is supportive of the proposed approach to develop a positive list of microorganisms, where known safe organisms are permitted, noting that all others must be evaluated for safety and approved or rejected accordingly. However, NSW also suggests that FSANZ consider the alternative approach of developing a negative list as was done by the European Union. The negative list would make it very clear on what is unacceptable and coupled with the positive list, would provide for clear regulation through the Code.

It may also be appropriate to consider including 'permitted characteristics' of microorganisms, for example; they do not produce toxins of known human health impact, and/or a known history of safe use with an established composition and method of production to facilitate innovation.

Expansion of Scope of Proposal 1024

NSW is supportive of the broadening of scope of Proposal 1024 to include *Standard 2.9.5 – Food for special medical purpose* as this standard currently permits the addition of foods used as nutritive substances. It would seem sensible to include this category of foods in this review process. NSW also notes the internal restrictions on supply of these foods provided by Standard 2.9.5-5.

NSW considers that expanding the scope of Proposal 1024 to include *Standard 2.9.2 – Foods for infants* will require careful consideration due to the specific needs of this vulnerable sub-population. NSW notes that certain foods within Standard 2.9.2 may be formulated for infants under the age of 6 months. NSW suggests that a similar approach to assessment is required for these foods as is required for foods regulated by *Standard 2.9.1 – Infant formula products*. NSW does not support extension of Proposal 1024 to Standard 2.9.1. NSW also suggests that current information in Standard 2.9.2-5 concerning claims for vitamins and minerals (and references to Schedule 29-11) should be retained following this process.

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.