SUBMISSION FROM SA HEALTH
28 July 2017
Consultation Paper - Proposal P1024
Revision of the Regulation of Nutritive Substances & Novel Foods

The purpose of this Proposal is to develop an improved framework for the regulation of nutritive substances and novel foods in the Australia New Zealand Food Standards Code (the Code).

SA Health welcomes the opportunity to provide comment on this consultation paper. SA Health generally agrees with other stakeholders that a new approach to regulating nutritive substances and novel foods is required.

SA Health in its submission (24 March 2016), did not support the self-assessment notification route for approval of nutritive substances and novel foods. This aligned with the views of other Government agencies on the proposed framework that were concerned about the lack of centralised, regulatory and scientific oversight as well as the potential for inconsistencies in determining compliance across jurisdictions (due to differing levels of resources and scientific expertise in jurisdictions).

This FSANZ consultation paper provides a modified framework (Attachment B to consultation paper) that does not include the self-assessment notification pathway. It only provides for the 'eligible food' criteria pathway and the FSANZ pre-market assessment pathway. The possible modified framework may be a better framework than the pathway provided in the original FSANZ consultation paper in 2016.

However, there is insufficient detail provided in the current FSANZ consultation paper to understand how the legal drafting of the pathway within the Food Standards Code would work and whether it would be readily enforceable by the jurisdictions. For this reason, SA Health awaits the opportunity to provide feedback on any draft food regulatory measure prepared and on the content of any such measure. The following comments are provided by SA Health to the specific questions for submitters to assist in development of the proposal.

Questions for submitters: Will the removal of permissions from Schedule 25 create problems relating to requirements for specifications for these foods?
Which of the novel foods listed in Schedule 25 are used only in foods regulated by specific Part 2.9 standards? Are there other issues associated with removing permissions from Schedule 25? Please elaborate.

Schedule 25 list the permitted novel foods and their conditions for use. The foods and nutritive substances listed in this schedule have been risk assessed by scientific evaluation of evidence of public health and safety.

Removal of the permissions would only have an effect where there is a specific condition of use specified within the schedule. If there is no specific condition of use required in Schedule 25, removal of the permission would have little effect on the use of the food as it would still be permitted as long as it is safe and suitable according to the Food Acts. This is the case with most foods that are not prescribed in food standards.

However if Schedule 25 is removed, for some food manufacturers and enforcement agencies there may be some uncertainty that the food listed in the Schedule 25 is still permitted since there would be no prescriptive permission in a standard that could be referenced.

Question for submitters: Do you consider other nutritive type substances (in addition to vitamins, minerals, electrolytes and L-amino acids) should always be subject to pre-market approval by FSANZ? Please provide reasons for your view.

Where a nutritive substance is added to a food for a specific nutritional function then it should always be subject to pre-market approval by FSANZ. This is the case for food additives, processing aids, vitamins, minerals, electrolytes and L-amino acids that require pre-market approval by FSANZ to ensure public health and safety and to meet the other objectives of the FSANZ Act. There is confidence in the risk assessments performed by FSANZ in the safety evaluation of substances added to food.

If the nutritive substance is added to food without a specific nutritive purpose it is being used as a food or food ingredient and so it should not require a pre-market approval. This is the case with most food and food ingredients that are required to be safe and suitable under the Food Acts of the State and Territories.

Questions for submitters: Does there remain a requirement to provide exclusive permission as a condition of use in the Code? What costs to the community, Government and industry arise from the grant and use of exclusive permissions? Please provide data if possible. What direct and indirect benefits to the community, Government and industry arise from the grant and use of exclusive permissions? Please provide data if possible. Why should Australian and New Zealand food laws make Australian and New Zealand food regulators bear the onus and cost of protecting industry's intellectual property in products being sold commercially? Why are other existing measures (such as intellectual property laws allowing a patent or innovation patent) not adequate to protect industry's investment in developing commercial food products? What other alternatives exist to protect industry's investment in developing commercial food products (i.e. other than reliance on the Code and Australian and New Zealand food laws)? Is the current 15-month period applied to exclusive permissions sufficient? If 15 months is not considered sufficient, please explain why this is the case and what period of time would be sufficient and why. Please provide data if possible. Does the innovation activity your business undertakes typically occur in Australia or New Zealand? Will this change if the period for exclusive permissions are increased and, if so, how and why? Please provide data if possible. Does your business typically place new products on the market at the same time or before placing them on the market in larger overseas markets? Please provide examples or data if possible.

Yes, support retaining exclusive permissions in the Code for foods approved by FSANZ. Exclusive permissions in the Code allow for clarity in interpretation and thus ease of communication, implementation and establishing compliance strategies. Exclusive permissions also encourage manufacturers to be innovative and cover cost of product development of new nutritive substances.

Questions for submitters: Please indicate whether you support the 'grandfathering' of foods which are available for sale in Australia and New Zealand at the time of gazettal (of a new framework in the Code). Do you consider there are categories of foods that should not be grandfathered? If so, please provide justification for your view. Would the proposed approach for microorganisms present problems for your business? If so, please elaborate.

The FSANZ consultation paper does not provide a definition of "grandfathering" or detail how grandfathering of foods would be established. This information is necessary before a decision to support can be made.

FSANZ sees merit in all foods produced with live food culture microorganisms sold in Australia and New Zealand at the time of gazettal being 'grandfathered' and not subject to the new framework. It is unclear how this positive list would be established by FSANZ nor how jurisdictions would be able to enforce such a list. It is suggested that FSANZ hold a workshop with jurisdictions and other stakeholders so that case studies can be explored to understand how such a system would work.

The asterisk box to Attachment B – Modified framework states that the food is only subject to the framework if it is NOT a food additive, processing aid, food produced using gene technology, irradiated food or a vitamin, mineral, L-amino acid or electrolyte. Many substances that are added to food may have multiple purposes or treatments applied to them, so they may fall under more than one of the above classifications for the purpose of regulation. It is not clear what is the intent or purpose of this statement? So it may be possible for example that a substance may serve a technological function and a nutritive function when added to a food.