Comments from the Victorian Department of Health and Human Services and the Victorian Department of Economic Development, Jobs, Transport and Resources

Due date of submission – 28 July 2017

The Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources (the departments) welcome the opportunity to provide comments on the consultation paper for Proposal P1024 – Revision of the regulation of nutritive substances and novel foods.

This submission provides general comments regarding the matters raised in the consultation paper rather than directly responding to the specific questions raised by Food Standards Australia New Zealand (FSANZ). It should be read in conjunction with the comments provided by the departments in response to FSANZ's first call for submissions in March 2016.

Consultation process and development of Eligible Food Criteria

The departments note that the consultation paper is an interim step between the two formal calls for public submissions. The paper seeks feedback on the proposed modified framework that removes the industry self-assessment pathway (presented in the first call for public submissions). Submitters are also asked to comment on the potential impact of the modified framework on existing Australia New Zealand Food Standards Code (the Code) provisions for novel foods, and on the issues of exclusivity of permissions and grandfathering of products already in the market.

The departments appreciate the intent of FSANZ's decision to restrict this call for submissions on the principles of the modified framework, rather than the detail associated with development of the Eligible Food Criteria. However it is our view that, with the removal of the self-assessment pathway, development of suitable Eligible Food Criteria are critical for ensuring that the modified framework effectively balances the safety of the community with support for an innovative food industry.

Given the complexity and possible contention that will be involved in developing these Eligible Food Criteria, the departments consider it may be necessary for FSANZ to undertake an additional round of consultation. This additional consultation should specifically seek comment on the proposed Eligible Food Criteria prior to any call for submissions on the draft Standard. The departments consider that, since FSANZ has already undertaken sufficient work on establishing the fundamentals of the Eligible Food Criteria, it should be possible to develop the consultation paper reasonably quickly. This would allow for the additional round of consultation to occur within FSANZ's existing timeframe for Proposal P1024.

Removal of a self-assessment pathway

The departments acknowledge the removal of a self-assessment pathway for industry due to issues raised by jurisdictions regarding enforcement (in particular concerns about lack of resources and expertise and the need for a consistent approach for the decentralised assessment of dossiers). The departments further note the constraints

imposed by the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) that restrict FSANZ's ability to provide a central mechanism for assessing dossiers.

To ensure that the proposed two-pathway approach for regulating new foods does not place unnecessary burden on industry, the departments support streamlining of the FSANZ pre-market assessment process. In the short term this could be achieved by amendments to the Application Handbook. In the longer term the departments support amendments to the FSANZ Act to allow FSANZ to assess dossiers held by food businesses.

Amendments to the FSANZ Act should be considered more generally to support the effective use of contemporary regulatory tools in the national food system, including industry self-assessment pathways. With appropriate underlying legislative support, industry self-assessment can provide a valid, proportionate and efficient tool to manage regulatory risks. For example, health claims are examples of areas of regulatory reform in which self-assessment could have been adequately supported by a process of central assessment, and determinations underpinned by a clear legislative basis.

Existing permissions for novel foods

With the removal of the definition of novel food from the Code, the departments recognise the need to determine a different approach to managing permissions for novel foods currently provided in Schedule 25 of the Code. This approach needs to provide certainty for industry but also ensure that novel foods with restricted conditions of use continue to be suitably regulated. The departments support these permissions being moved to existing or new standards as appropriate.

Nutritive and related substances

The departments note the problems associated with the current definition of nutritive substance in the Code and support its removal. As such, the requirement for "nutritive type substances" to have a pre-market approval will be determined by whether these foods sit outside the Eligible Food Criteria or are subject to a separate requirement for a pre-market approval (for example, as proposed by FSANZ for vitamins and minerals).

FSANZ has sought comments on whether other "nutritive type substances" should always require pre-market approval. The departments suggest that this question should be considered as part of the development of the Eligible Food Criteria.

Determination of how "nutritive type substances" are dealt with by the Code will have consequences for the Infant Formula review Proposal P1028. The departments support the current restrictions on the addition of substances to infant formula.

Exclusive permissions

In endorsing the Ministerial Policy Guideline for novel foods, ministers recognised the importance of supporting an assessment process for new products that protects commercially sensitive information and recognises industry's intellectual property. The departments note that by providing first-to-market opportunities for businesses, exclusive permissions for use of novel foods support this principle and can incentivise innovation in the food sector. The departments therefore support continuation of

exclusive permissions for use if the applicant can provide evidence to show investment in innovation associated with the new product.

The case for making a change to the period of exclusivity of use does not appear to be supported by a significant body of evidence. For foods whose development involves a greater degree of inventiveness or innovation, a longer period of exclusivity of use may be justified to represent an adequate return on investment for the food industry.

Transition arrangements for foods and substances currently sold

i) Grandfathering provisions

The departments question the need to include grandfathering provisions in the framework for nutritive substances and novel foods. Grandfathering of an undefined group of foods and substances is likely to lead to ongoing uncertainty in the market place. If the new framework, including development of the Eligible Food Criteria and management of existing permissions for novel foods, is truly reflective of the risk associated with foods and substances, then it should apply to all foods and substances, including those already sold.

If FSANZ undertakes an additional round of consultation on the development of the Eligible Food Criteria, as suggested by the departments, this would provide an opportunity to work through issues associated with the application of the new framework to foods and substances already being sold.

ii) Other transitional issues

The approach to food products with live food culture microorganisms (FCM) should be considered as part of the development of the Eligible Food Criteria and should support the continued use of FCMs in yogurt, cheese and wine. FSANZ might also note the use of FCMs in brewed soft drinks (Standard 2.6.2) and also the intentional presence of microorganisms in food that are not FCMs, such as some probiotic bacteria.