Comments from the Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions and PrimeSafe.

Due date of submission – 14 February 2020

The Victorian Departments of Health and Human Services and Jobs, Precincts and Regions (the departments) and PrimeSafe welcome the opportunity to respond to this application to amend the Australia New Zealand Food Standards Code (the Code).

Application A1186 - Soy leghemoglobin in meat analogue products seeks to amend the Code to permit the use of soy leghemoglobin from the yeast *Pichia pastoris* (*P. pastoris*) as a component in meat analogue products. Soy leghemoglobin is derived from a cell lysate preparation of the genetically modified *P. pastoris*.

From the Food Standards Australia New Zealand (FSANZ) assessment report it is understood that:

- Soy leghemoglobin is intended to replicate the nutrition (that is, source of iron), flavour and aroma of myoglobin.
- The yeast strain (MXY0541) has been genetically modified to express the leghemoglobin gene from soybean.
- Leghemoglobin is a globulin protein and typically expressed in the root nodules of leguminous plants.
- The applicant manufactures soy leghemoglobin in the form of LegH Prep to produce meat analogue products in the US and intends to import these products as raw, frozen and packaged products into Australia and New Zealand for distribution in quick service restaurants and supermarkets.
- Internationally, meat analogue products containing LegH Prep are permitted in the US, Singapore, Hong Kong and Macao at levels of 0.45 and 0.8% soy leghemoglobin.
- FSANZ assessed soy leghemoglobin as a food produced using gene technology and as a permitted form of iron.
- FSANZ's risk assessment has concluded that there are no safety risks for soy leghemoglobin consumption in the form of LegH Prep at levels up to 0.8%.

This application is complex, and it is the view of the departments and PrimeSafe that a number of important concerns must be addressed before this Application can proceed. In particular, the quality of the risk assessment information provided in order to ensure the protection of public health and safety is inadequate. The departments and PrimeSafe are not satisfied that the risk assessment has adequately assessed the safety of this product for Australian and New Zealand consumers, and **request that FSANZ convenes a jurisdictional working group to understand and resolve concerns associated with Application A1186.**

Specific matters related to safety that the departments and PrimeSafe seek further information on include:

Safety and risk assessment of the proposed LegH Prep for human consumption

As acknowledged in the application, the yeast strain (MXY0541) is different to the strain that was given Generally Regarded as Safe (GRAS) status in the USA (MXY0291) and is a different strain to that used to generate the information for the risk assessment and dietary exposure trial. The application appears to draw on data from MXY0291 by referring to the publication by Jin et al. (2017) as evidence for no allergenicity and toxicity, and the departments and PrimeSafe seek clarification as to whether the supporting safety data relates to strain MXY0541 or strain MXY0291 and calls for safety data on the specific production strain related to this application.

The departments and PrimeSafe consider that there is **insufficient evidence** in the risk and technical assessment report regarding both the unintended generation of proteins from new open reading frames (ORFs) through the genetic insertion events, and the uncertainty of carry over proteins from *P. pastoris* in the LegH Prep. Given the reported inconsistency of carry over *P. pastoris* proteins in different batches of LegH Prep, and the limited number of proteins that were characterised *in silico* for toxicity and allergenicity, the departments and PrimeSafe **do not consider that the full potential for the toxicity and allergenicity posed by LegH Prep has been adequately addressed.**

There is a paucity of independent scientific research and a lack of alternative risk assessment reports available on LegH Prep. Almost all the information was generated by the applicant or through the applicant's funded projects and thus it is difficult to access and verify where information is missing. Moreover, the feeding trial data supplied is insufficient in the duration of animal feeding and in the method of feeding, which does not appear to reflect human consumption patterns. The departments and PrimeSafe are concerned that this feeding trial data cannot be appropriately translated to ensure there is no toxicity for human consumers.

The Application assessment approach

In this application FSANZ has assessed soy leghemoglobin as a food produced using gene technology and as a permitted form of iron. The departments and PrimeSafe suggest that this food could be assessed as a novel food or even as a food additive, as the substance has a technological function being 'to replace the flavour and aroma of the myoglobin'. We seek further information from FSANZ regarding the approach taken with this Application, and advice from FSANZ regarding the likely labelling and health claims restrictions that will apply to this food.

The departments and PrimeSafe:

Do not support the progress of Application A1186 to allow an amendment to the Code to permit the use of soy leghemoglobin from *Pichia pastoris* as a component in meat analogue products at this stage.

The departments and PrimeSafe have concerns about the risk assessment information presented in the application. There is a lack of independent scientific research-based information available on the safety and health risks of the ingredients and the final product.

Considering the complexity and concerns around the Application A1186, we request that FSANZ convenes a jurisdictional working group to discuss and address these and other issues before there is further progress on this Application.