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 – 17 September 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 second Call for Submissions to amend the Australia New Zealand Food Standards Code (the Code).

Application A1186 - Soy leghemoglobin in meat analogue products, submitted by Impossible Foods, seeks to amend the Code to permit the use of soy leghemoglobin in meat analogue products such as the Impossible Burger, meatballs, sausages, and as fillings in buns and dumplings. It is understood that:

- Permission is sought for soy leghemoglobin as a novel food, nutritive substance and genetically modified (GM) food.
- The level of soy leghemoglobin proposed for use in meat analogue products is not more than 0.8% weight for weight (w/w2) in raw product.
- Soy leghemoglobin is a liquid cell lysate preparation (LegH Prep) that is produced using a GM yeast, *Pichia pastoris*.
- FSANZ has assessed soy leghemoglobin as a nutritive substance and a food produced using gene technology.
- Soy leghemoglobin has not been assessed as a novel food.

The departments and PrimeSafe recognise that fast-paced innovation in the alternative protein sector is taking place. Industry in Australia and New Zealand wishes to access commercial opportunities such as this for international consistency and competitiveness. There will be opportunities for businesses in Australia and New Zealand to earn revenue by purchasing and selling Impossible branded meat analogue products containing soy leghemoglobin. Our comments, however, place public health and safety at the centre of new regulation and policy development.

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 final ingredient.

In response to first Call for Submissions, the position of the departments and PrimeSafe was:

'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.'

The response from FSANZ included in the second Call for Submissions has not adequately addressed those concerns.

It is acknowledged that the concern raised by the departments and PrimeSafe about the assessment of the LegH Prep as a nutritive substance has been addressed in the second Call for Submissions. FSANZ's assessment has considered the LegH Prep as a GM food because of its nature (a food produced using gene technology) and as a source of iron in meat analogue products. According to FSANZ, the consideration of the LegH Prep as a food additive has no justification.

Rationale

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

The permission is sought to use soy leghemoglobin-containing LegH Prep produced from a GM *P. pastoris* strain MXY0541. Our concerns are that most of the information used for the risk and dietary exposure assessment was generated using a different strain (MXY0291). It is acknowledged in the application that the yeast strain (MXY0541) is different to the strain (MXY0291) that was given Generally Regarded as Safe (GRAS) status in the USA. FSANZ's risk assessment also indicates that several genetic and functionality differences exist between the two strains. The safety data presented was drawn from the MXY0291 strain, referring to the publication by Jin et al. (2017)[1] as basis that there is no evidence for allergenicity and toxicity. The departments and PrimeSafe consider it is important to have safety data on the specific production strain (MXY0541) related to this application.

FSANZ has included information on the bioavailability of haem iron from soy leghemoglobin in an Impossible Foods meat analogue product in the risk assessment. It is equally important to assess the microbiological safety of Impossible Foods meat analogue products. Recently, a peer-reviewed research article concluded that the plant-based meat analogue food matrix provides conditions more favourable for pathogenic bacterial growth than meat-based counterparts (Luchansky et al., 2020)[2]. Microbiological risk assessment data for the Impossible Foods meat analogue products is missing from the FSANZ's risk assessment document.

[1] Jin Y, He X, Andoh-Kumi K, Fraser RZ, Lu M, Goodman RE (2018) Evaluating potential risks of food allergy and toxicity of soy leghemoglobin expressed in *Pichia pastoris*. Mol Nutr Food Res 62:e1700297.
[2] Luchansky JB, Shoyer BA, Jung Y, et al. (2020) Viability of Shiga toxin-producing *Escherichia coli*, *Salmonella*, and *Listeria monocytogenes* within plant versus beef burgers during cold storage and following pan frying. J Food Prot 83(3):434-442.

This omission emphasises the concern expressed by the departments and PrimeSafe in the first Call for Submissions. That concern being that almost all the information provided was generated by the applicant or through the applicant's funded projects. It is therefore difficult to access and independently verify where information is missing. The availability of independent research data would provide unbiased information on unconsidered aspects of risk assessment of such substances and food produced using them.

The departments and PrimeSafe note that the European Food Safety Authority (EFSA) is currently conducting a risk assessment of soy leghemoglobin produced from GM *P. pastoris*. To continue assessing this Application in the light of a risk assessment process that would inform FSANZ's own assessment, seems premature. The departments and PrimeSafe seek advice from FSANZ as to possible actions if EFSA's assessment concludes that there are potential public health risks related to the consumption of this compound.

The position of the departments and PrimeSafe remains unchanged in that there is lack of independent scientific research, and insufficient evidence in the risk and technical assessment report regarding health and safety protection for consumers.