Queensland Government

Enquiries to: Food Safety Standards and Regulation
Health Protection Branch
Telephone: (07) 3328 9310

Queensland Health

Standards Management Officer
Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604

standards.management@foodstandards.gov.au

Dear Sir / Madam

Submission: A1186 – Soy leghemoglobin in meat analogue products

Thank you for the opportunity to provide a submission for Application A1186.

This submission provides technical advice and comments related to this issue. The submission does not represent a Queensland Government position, which will be a matter for the Queensland Government when notification is made by the FSANZ Board to the Australia and New Zealand Ministerial Forum on Food Regulation.

Queensland Health notes that the purpose of Application A1186 is to seek permission to use soy leghemoglobin, in the form of LegH Prep, as a nutritive substance (source of iron) in meat analogue products. However, according to Application A1186, soy leghemoglobin (LegH Prep) fulfils other technological functions as it improves the appearance, flavour and aroma profile of a meat analogue product to align it more closely with meat. Queensland Health notes that the applicant, Impossible Foods, obtained self-affirmed FDA GRAS status to use soy leghemoglobin at levels up to 0.8% in its raw minced beef analogue products as a flavour optimiser (in July 2018), and as a permitted colour additive (in September 2019).

The proposed use of soy leghemoglobin in meat analogue products means that they will more closely simulate meat, particularly in terms of iron content. For example, a meat analogue product containing leghemoglobin could carry the nutrient content claim ‘good source of iron on the label. The equivalence of plant-derived analogue foods with their counterpart dairy and meat food products is a contemporaneous issue bringing into question the use of the terms, ‘milk’ and ‘meat’, which does not appear to be yet resolved within the national food regulatory space.

Although the purpose of Application A1186 is to seek permission to use leghemoglobin, derived from soy, and produced by a genetically modified (GM) strain of *Pichia pastoris* (MXY0541), specifically in meat analogue products, it is reasonable to anticipate that approval of Application A1186 may open the ‘floodgates’ to other applications involving leghemoglobins derived from different crops (e.g. alfalfa) using different source microorganisms and added to different foods. This could induce the release a ‘raft’ of

applications which FSANZ would need to consider individually, as has occurred with steviol glycosides.

Further reflection should be given to how LegH Prep will be declared on a label of a food because it is a preparation rather than a single substance, e.g. should it be listed as a food or ingredient in the ingredients list. Because it performs multiple technological functions in a food, e.g. as a colour, flavour and odour enhancer/optimiser and source of iron, consideration is required as to whether the existing functions of food additives provided in Schedule 14 —*Technological purposes performed by substances used as food additives* adequately describe the technological purposes for which LegH Prep may be added to a food.

If soy leghaemoglobin is permitted as a nutritive substance in meat, it may provide fresh colour, and subsequent longer shelf life, to a meat product that would otherwise appear unacceptable due to the loss of its fresh red colour. In other words, the use of leghemoglobin may have the potential to cause similar food safety issues to carbon monoxide treatment of seafood, which is specifically prohibited in the Food Standards Code Standard 1.3.3—*Processing Aids*. The relative stability of soy leghemoglobin and myoglobin in meat analogues may need to be determined.

A supplementary issue relating to the addition of leghemoglobin to meat is that leghemoglobin is released from tissue at a lower temperature than myoglobin meaning that meat may appear cooked when in fact it is not. Information was not provided in Application A1186 about whether Impossible burger and other meat analogues require cooking in order to be safe. If this is so, FSANZ may need to consider a mandatory direction for use for safety.

It may not be possible to regulate the amount of soy leghemoglobin added to a meat analogue. Queensland Health Forensic and Scientific Services (FSS) laboratory has advised that it does not have a validated method for the analysis of soy leghemoglobin in food. Standards of soy leghemoglobin appear to be difficult to source. FSS can test for the total iron content in a food containing LegH Prep but it will not be able to discriminate iron from soy leghemoglobin from endogenous iron. FSS is unable to detect the leghemoglobin GM event in food products. Application A1186 does not provide any information about Impossible Foods will provide a test protocol for the detection of soy leghemoglobin in meat analogue products suitable for regulatory purposes.

Should Application A1186 be approved, a specification for soy leghemoglobin will be required in Schedule 3 — *Identity and purity* in the Food Standards Code. This may be difficult when LegH Prep is a partially purified lysate of a fermentation culture of *P. pastoris*. The supporting document (SD1) to Application A1186 states that different proteins are present in the *P. pastoris* MXY0541 cell lysate, depending on the growth phase of individual cells in the culture when fermentation ends. It is acknowledged, however, according to SD1, Impossible Foods *have demonstrated that they have in-process controls in place to ensure the purity and consistency of the final preparation* and that the *LegH Prep is well characterised and meets food-grade specifications.*

Should Application A1186 be approved, soy leghemoglobin will need to be added to Schedule 26 — *Food produced using gene technology* as a permitted GM food. Currently Schedule 26 comprises GM crops, such as herbicide resistant corn. Inclusion of a GM food, such as LegH Prep, in Schedule 26 will markedly change the type of foods included in this Schedule.

In FSANZ's safety assessment of the allergenicity and toxigenicity of soy leghemoglobin, it appears that not all proteins produced by MXY0541 have been studied. Toxicological assessment of LegH prep was assessed using LegH Prep from MXY0291, a predecessor of strain MXY054. FSANZ considered LegH Prep from both MXY0291 and MXY0541 were equivalent. However, concern is raised because there are differences between the two preparations, as shown in Table 1 of SD1. When assessing safety of native *Pichia* proteins present in LegH Prep from MXY0291 and MXY0541, FSANZ notes that not all preparation contained the same proteins at the same levels because protein type and concentration depend on the cell cycle stage of each cell at the time the fermentation run was completed. This raises the question as to whether the allergenicity and toxigenicity of all proteins in the partially purified LegH Prep cell culture have been determined.

Queensland Health would welcome the opportunity to further discuss the Application with you including an interjurisdictional workshop if necessary. Thank you, once again, for the opportunity to provide a submission for Application A1186.

Kind regards

Food Safety Standards and Regulation Unit
Health Protection Branch
Department of Health
Queensland Government

14 February 2020