



14 February 2020

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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the *Call for submissions – Application A1186: Soy leghemoglobin in meat analogue products*.

Yours sincerely



***Call for submissions – Application A1186:
Soy leghemoglobin in meat analogue
products***

**Submission by the New Zealand Food & Grocery
Council**

14 February 2020

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council (“NZFGC”) welcomes the opportunity to comment on the ***Call for submissions – Application A1186: Soy leghemoglobin in meat analogue products.***
2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over \$40 billion in the New Zealand domestic retail food, beverage and grocery products market, and over \$34 billion in export revenue from exports to 195 countries – representing 65% of total good and services exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 45% of total manufacturing income. Our members directly or indirectly employ more than 493,000 people – one in five of the workforce.

The Application

3. Impossible Foods Inc is a Californian company producing plant alternatives to animal products such as meat, fish and dairy. The company commercialised the Impossible™ Burger in 2016. The burger has been subsequently served on Air New Zealand flights from Los Angeles to Auckland.
4. Impossible Foods now wants the soy leghemoglobin (used in the LegH Prep which in turn is used in the Impossible™ Burger) to be included in the Food Standards Code so that it might be added to other meat analogue products to provide nutrition (such as iron), flavour and aroma of the traditional animal derived counterpart. Soy leghemoglobin is a component of a cell lysate preparation from a genetically modified (GM) yeast, *Pichia pastoris*. The intention is that soy leghemoglobin would be used at levels up to 0.8% weight for weight in raw product.

OVERARCHING COMMENTS

5. NZFGC supports the inclusion of soy leghemoglobin in the Food Standards Code. We note that the risk assessment conducted by FSANZ addressed the safety of the *P. pastoris* host strain, novel proteins, toxicity of the preparation, a nutritional and dietary intake assessment and an assessment of the gene insertions applied. There were no safety concerns in the safety assessment.
6. FSANZ proposes a maximum permitted use level of 0.8% as applied for and that the generic labelling provisions in Standard 1.2.4 of the Food Standards Code will apply. Additionally, since novel DNA and novel protein from GM *P. pastoris* will be present in the final food product from the LegH Prep ingredient, products containing LegH Prep will need to be labelled as GM at retail and relevant information must be available on request from a consumer by a food business supplying food for immediate consumption (fast food) or by a caterer.
7. Internationally the US, Canada, Singapore and Hong Kong/Macau have approved use and approval in the EU is pending. Impossible Foods has stated that over 20 million servings of meat analogue products containing LegH Prep have been served since June 2016 and products have been sold in restaurants in Hong Kong, Macau and Singapore. There have been no reported adverse effects from the consumption.
8. NZFGC supports FSANZ proceeding with the application on the basis of safety, product innovation and providing consumer choice.

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9. FSANZ proposes undertaking two rounds of consultation should the application proceed, instead of just one. However, if the application is rejected, we would like to be informed of the basis for the rejection since the evidence is clear that the product is safe for consumption and has been accepted for use in several jurisdictions overseas.

DETAILED COMMENTS

10. Impossible Foods applied for soy leghemoglobin to be included in the Food Standards Code as a novel food, a nutritive substance and a food produced using gene technology. We note that FSANZ has chosen to assess soy leghemoglobin as a food produced using gene technology. We note that a footnote 2 in the Call for Submissions advises that, after reviewing internal processes on how to assess applications involving GM, FSANZ has decided that any application related to a GM food would not be assessed as a novel food. NZFGC suggests that FSANZ might publish its rationale for reaching this decision in the interests of transparency.

Risk Assessment

11. FSANZ conducted a risk assessment that addressed the safety of the *P. pastoris* host strain, novel proteins, toxicity of the preparation, a nutritional and dietary intake assessment and an assessment of the gene insertions applied.
12. In relation to the safety of the *P. pastoris* host strain, it has been used for around 40 years and is the preferred organism for the production of heterologous proteins. FSANZ examined the heritage of the substance noting that two derived organisms are both classified as safe by the US Public Health Service and the European Food Safety Authority. *P. pastoris* is related to bakers' and brewers' yeast and has a long history of safe use in the food supply.
13. A large and diverse range of proteins are ingested as part of a normal human diet. The soy leghemoglobin protein does not share similarity to any known protein toxins, or allergenicity. FSANZ concluded there were no safety concerns identified regarding the potential allergenicity or toxicity of soy leghemoglobin or the *P. pastoris* proteins. Similarly, the LegH Prep was not genotoxic *in vitro* and did not cause adverse effects in short-term toxicity studies in rats.
14. In relation to the nutrition and dietary intake assessment, FSANZ noted that around 15-25% of haem iron in the diet is absorbed compared to 5-12% of non-haem iron. The bioavailabilities of soy leghemoglobin and bovine haemoglobin are likely to be similar (based on evidence provided by the applicant). As a result, the proposed meat analogue products containing soy leghemoglobin present no nutritional disadvantages to consumers in Australia and New Zealand. Dietary intake of iron contributed by soy leghemoglobin was estimated as falling within the upper limits for iron for the population for both the maximum proposed use level and the likely use level and that this would pose no risk of iron exceedances to the Australian and New Zealand populations.
15. NZFGC suggests that there would likely be a positive impact for vegans and vegetarians of the product since their intakes of iron rich products tend to be lower in any case.
16. Ten genes have been inserted into the *P. pastoris* host in order to express soy leghemoglobin. FSANZ considered the data provided in the production and insertion process and subsequently determined these posed no safety concerns.

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17. We note that Impossible Foods is seeking a patent in Australia and New Zealand for the methods of production and specifications for the product which would sit alongside the approval in the Food Standards Code.

Risk Management

18. FSANZ proposes a maximum permitted use level of 0.8% as applied for although it notes the upper level approved by Singapore is lower than is being proposed for Australia and New Zealand. We note FSANZ is trying to find out the rationale for this and assume this could influence the final decision on the maximum permitted use level.
19. In terms of labelling, generic labelling provisions in Standard 1.2.4 of the Food Standards Code will apply. Additionally, since novel DNA and novel protein from GM *P. pastoris* will be present in the final food product from the LegH Prep ingredient, products containing LegH Prep will need to be labelled as GM at retail but not when used in food for immediate consumption (fast food). However, the information must be available on request from a consumer at the time of prospective consumption by a food business or through a caterer.

International use

20. Internationally the soy leghemoglobin ingredient has been successfully reviewed for use in the US, Canada, Singapore and Hong Kong/Macau. Approval in the EU is pending. Impossible Foods has stated that over 20 million servings of meat analogue products containing LegH Prep have been served since June 2016 and products have been sold in restaurants in Hong Kong, Macau and Singapore. There have been no reported adverse effects from the consumption.

Conclusion

21. NZFGC supports FSANZ proceeding with the application on the basis of safety, product innovation and providing consumer choice.
22. We do note that the Call for Submissions dated 20 December 2019 from FSANZ is the first of two Calls for Submission. We would have expected the title to have read "1st Call for Submissions" as is usual practice to signal this upfront. This simply makes it clearer for submitters.
23. Further, we note that FSANZ states that in undertaking two rounds of consultation instead of just one in relation to Application A1186, its purpose is to inform the decision to proceed or reject the application.
24. It is of considerable concern to us to understand what the basis for rejecting the application would be if the evidence is clear (as it is) that the product is safe for consumption and has been accepted for use in several jurisdictions overseas. Other than the application having been assessed as a food produced using gene technology rather than as applied for, as a novel food, there seems no reason that a draft amendment to the Food Standards Code was not prepared for a single round of submissions.