6 August 2020
[131–20]

2nd Call for submissions – Application A1186

Soy leghemoglobin in meat analogue products

Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist FSANZ's consideration of the draft food regulatory measure it has prepared arising from an application made by Impossible Foods Inc. for the voluntary addition of soy leghemoglobin, produced by microbial fermentation, in meat analogue products.

For information about making a submission, see the information for submitters on our website.

All submissions on applications and proposals will be published on our website. We will not publish material that that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on documents for public comment. You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 17 September 2020

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters. Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting documents

The following documents which informed the assessment of this Application are available on the FSANZ website:

SD1	Risk and technical assessment report
SD2	Consumers and meat analogue products in Australia and New Zealand

Executive summary

Impossible Foods (the applicant) applied to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of soy leghemoglobin[1] in meat analogue products (including the Impossible burger, meatballs, sausages, and as fillings in buns and dumplings) at levels not more than 0.8% weight for weight (w/w[2]) in raw product.

The applicant sought permission for soy leghemoglobin as a novel food, nutritive substance and genetically modified (GM) food. The applicant's use intends to provide the nutrition (source of iron), and flavour and aroma similar to that of myoglobin, an oxygen storing haem protein found in meat.

The applicant's soy leghemoglobin is presented in the form of a liquid cell lysate preparation (called LegH Prep[3]) and is produced from a GM yeast, *Pichia pastoris*. This yeast has been modified to express the leghaemoglobin gene from soybean *(Glycine max*). LegH Prep contains soy leghemoglobin, proteins and genomic DNA from the *Pichia* production strain, plus sodium ascorbate and sodium chloride as stabilisers.

FSANZ has assessed soy leghemoglobin as a nutritive substance for the purpose of providing a source of iron to meat analogue products. FSANZ also assessed soy leghemoglobin in the form of LegH Prep as a food produced using gene technology, due to its production method.

FSANZ did not assess soy leghemoglobin in the form of LegH Prep as a novel food because the GM and nutritive substance permissions more accurately reflect the nature of this ingredient (produced through microbial fermentation of a GM yeast) and the purpose for which it is being added to meat analogue products (as a source of iron).

FSANZ's risk and technical assessment (SD1) has used internationally agreed practices and processes to assess safety. Post-marketing surveillance data provided by international regulatory partners has not identified any confirmed adverse events following consumption of meat analogue products containing soy leghemoglobin in the form of LegH Prep. This is consistent with data provided by the applicant and the outcomes of FSANZ's safety assessment.

The applicant currently manufactures soy leghemoglobin in the form of LegH Prep for use in Impossible meat analogue products sold in the United States (US), Singapore, Hong Kong and Macau. As of 2019, soy leghemoglobin has regulatory approval for sale in meat analogue products in Canada.

On 20 December 2019, FSANZ sought submissions on its preliminary position in the 1st Call for Submissions (CFS) report; 44 submissions were received. FSANZ subsequently conducted targeted consultation with four Australian jurisdictions and the New Zealand Ministry for Primary Industries. Issues raised in submissions were also considered with additional input requested from the applicant.

Submissions received by FSANZ did not provide any substantive scientific evidence or new arguments that would change the conclusions of FSANZ's evaluation of the safety of soy leghemoglobin in the form of LegH Prep. FSANZ therefore maintains its overarching

[1] FSANZ recognises that, in Australia and New Zealand, the English spelling of 'haem' is more commonly used than 'heme', however the name 'soy leghemoglobin' is a product name used by the applicant. FSANZ will hereafter use 'soy leghemoglobin', 'leghaemoglobin' and 'haem', as applicable.
[2] 'weight for weight' or 'w/w' means 0.8 g/100 g.
[3] For the purposes of the draft variation, LegH Prep is referred to as a 'soy leghemoglobin preparation'.

conclusion at the 1st CFS that soy leghemoglobin in the form of LegH Prep is safe for human consumption in meat analogue products at levels up to 0.8%. This was based on the following key findings from the risk and technical assessment report (SD1):

- The applicant provided sufficient data to support the stability of soy leghemoglobin in the food matrix.
- Assessment of the source organism, *P. pastoris* and novel proteins, did not identify any public health and safety concerns.
- The source organism is a well characterised yeast with a recognised safe history of use for the production of food enzymes; it is neither pathogenic nor toxigenic.
- Analyses of the potential allergenicity or toxicity of all the novel proteins, including soy leghemoglobin and the *Pichia* proteins, did not identify any significant similarities to known allergens or toxins.
- *In vitro* genotoxicity studies in bacterial and mammalian cells and an oral toxicity study in rats confirmed the outcome of the compositional and bioinformatic analysis. No hazard was identified in the submitted studies. LegH Prep was not genotoxic in vitro and did not cause adverse effects in short-term toxicity studies in rats.
- Haem iron from soy leghemoglobin is likely to have similar bioavailability to haem iron from mammalian haem proteins (e.g. myoglobin present in muscle tissue).
- Based on a conservative dietary intake assessment that likely overestimated dietary intakes for LegH Prep and iron, Australian and New Zealand consumers will not exceed the upper level of intake (UL) for iron.

FSANZ has assessed the proposed use against the criteria and objectives prescribed by section 29 and 18 of the FSANZ Act. In doing so, we have given regard to relevant Ministerial Policy Guidelines, *Ministerial Policy Guideline for the fortification of foods with vitamins and minerals*[4] in relation to soy leghemoglobin as a form of iron. FSANZ considers the requirements of this Guideline have been met.

Based on that assessment, FSANZ has prepared a draft variation to the Code to permit the voluntary addition of soy leghemoglobin in meat analogue products at levels up to 0.8% in raw product. FSANZ now seeks comments on this draft variation, which is based on the regulatory approach summarised as follows:

- The soy leghemoglobin preparation (also known as LegH Prep) is defined in subsection S26—2(2) as 'a cell lysate preparation that is derived from *Pichia Pastoris* containing the gene for leghemoglobin c2 from *Glycine max*; and contains soy leghemoglobin'.
- Permission for the soy leghemoglobin preparation (LegH Prep) as a food produced using gene technology including the same gene-gene donor source, and specific conditions of use are inserted in a table in subsection S26—3(7) (Food produced using gene technology of microbial origin).
- Soy leghemoglobin is permitted as a substance *used as a nutritive substance* only in meat analogue products to which subsection S17—4 applies, with a maximum permitted use level of 0.8% in raw product, in accordance with Standard 1.3.2, and as a permitted form of iron in the table to section S17—3.
- Specifications for the identity and purity of a soy leghemoglobin preparation, as it is a delivery vessel for soy leghemoglobin, are provided in Schedule 3.
- Existing labelling requirements apply to enable consumers to make informed choice.

The proposed permissions support greater international consistency and trade opportunities, as soy leghemoglobin is currently permitted for use in meat analogue products in overseas

[4] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-for-the-Fortification-of-Foods-with-Vitamins-and-Minerals

markets. The permissions also provide alternative options to consumers wishing to reduce or eliminate their intake of meat, and promotes an innovative and competitive industry in Australia and New Zealand.

1 Introduction

1.1 The Applicant

Impossible Foods Inc. (Impossible Foods) was founded in 2011 in the United States (US) with the goal of producing sustainable plant-based alternatives to meat, fish and dairy foods. The first product to be commercialised by the company was the Impossible Burger in 2016.

1.2 The Application

The applicant seeks to amend the Australia New Zealand Food Standards Code (the Code) to permit the voluntary use of soy leghemoglobin, produced by genetically modified (GM) yeast *Pichia pastoris (P. pastoris)* as a component in meat analogue products (including the Impossible Burger, meatballs, sausages, and as fillings in buns and dumplings). This yeast has been modified to express the leghaemoglobin gene from soybean *(Glycine max*) and other host proteins that support the expression of leghaemoglobin. Products containing soy leghemoglobin are intended for consumption by the general population aged 2 years and older.

The application sought to include soy leghemoglobin in the Code as a novel food (Schedule 25), a nutritive substance (Standard 1.3.2 and Schedule 17), and food produced using gene technology (Schedule 26). Identity and purity specifications were provided for LegH Prep (Schedule 3). FSANZ understands the applicant has applied for patents in Australia and New Zealand for the methods of production and specifications for their meat analogue products, LegH Prep (containing soy leghemoglobin) product[5].

The applicant indicates the purpose of soy leghemoglobin is to provide a nutritional source of iron, flavour and aroma similar to that of myoglobin, a haem-containing protein found in the muscle tissue of animals (Ordway and Garry 2004).

The applicant states that soy leghemoglobin would be added to the applicant's meat analogue products in the form of LegH Prep, a liquid cell lysate preparation. Other substances in LegH Prep include residual GM *P. pastoris* cell components such as proteins and genomic DNA, and added stabilisers (e.g. sodium ascorbate and sodium chloride). Due to its production method FSANZ assessed soy leghemoglobin in the form of LegH Prep as a GM ingredient.

The maximum proposed use level for soy leghemoglobin is proposed by the applicant to be 0.8% (0.8 g/100 g) in raw product; this was proposed because it is at the lower end of the myoglobin content of red meat (0.8–1.8%) (Texas A&M Institute, 2019), and the applicant's testing has indicated it is the maximum addition level at which meat analogue products retain palatability. The application indicates that soy leghemoglobin levels currently used in raw beef and pork analogue products are 0.45% and 0.25% respectively, to obtain flavouring profiles similar to beef or pork meat products. Maximum use levels are usually set higher than intended use levels to allow for variability from batch to batch, and additionally a higher use level provides opportunity for product reformulation.

The applicant initially plans to import packaged raw and frozen Impossible meat analogue products into Australia and New Zealand for sale to retail and catering outlets. The applicant has advised that LegH Prep will not be sold for general use, but only as an ingredient of Impossible branded meat analogue products. The applicant has indicated that Australian and New Zealand co-manufacturers may be contracted in the future to locally produce Impossible

[5] FSANZ searched for "impossible foods" on New Zealand Intellectual Property Office and IP Australia websites.

meat analogue products, however the production of the LegH Prep ingredient will continue in an Impossible Food's production facility located outside Australia and New Zealand to ensure quality control.

1.3 The current standard

1.3.1 Australia and New Zealand

Australian and New Zealand food laws require food for sale to comply with the following Code requirements.

1.3.1.1 Permitted use

Used as a nutritive substance

Paragraph 1.1.1—10(6)(b) requires that, unless expressly permitted, a food for sale must not have as an ingredient or component a substance that is *used as a nutritive substance*. According to section 1.1.2—12, a substance is used as a nutritive substance in relation to a food if:

- it is added to the food to achieve a nutritional purpose; and
- it is either:
  - any substance identified in the Code as a substance that may be used as a nutritive substance; or
  - a vitamin or mineral; or
  - any substance that has been concentrated, refined or synthesised to achieve a nutritional purpose when added to the food (other than an inulin-type fructan, a galacto-oligosaccharide, or a substance normally consumed as a food).

Standard 1.3.2 provides for when a substance, such as a vitamin or mineral, may be permitted to be used as a nutritive substance in food. Section 1.3.2—3 states that a vitamin or mineral may be used as a nutritive substance in food if:

> *(a) the vitamin or mineral is in a permitted form specified in section S17—2 or section S17—3; and*
> *(b) the vitamin or mineral is listed in relation to that type of food in section S17—4; and*
> *(c) the total amount of the naturally occurring and added vitamin or mineral present in a *reference quantity of the food is no more than the amount (if any) specified in relation to that vitamin or mineral in section S17—4.*[6]

For permission to use soy leghemoglobin (in the form of LegH Prep) as a form of iron in meat analogue products to which section S17—4 applies, i.e. as a nutritive substance, then soy leghemoglobin will have to be listed in section S17—3 as a form of iron.

The table to section S17—4 already permits addition of iron to meat analogues providing the meat analogues meet specific protein conditions: *where no less than 12% of the energy value of the food is derived from protein, and the food contains 5 g protein per serve of the food.*

Since soy leghemoglobin (in the form of LegH Prep) is proposed to be used as a source of iron, meat analogues containing soy leghemoglobin would have to meet these conditions.

[6] The meaning of 'reference quantity' is provided in subsection 1.1.2—2(3) of the Code.

The total iron content of meat analogues is indirectly controlled by a 'maximum claim per reference quantity (maximum percentage RDI claim)' i.e. 30% RDI/100 g reference quantity. No additional 'maximum permitted amount per reference quantity' is set for iron.

Food produced using gene technology

Paragraphs 1.1.1—10(5)(c) and 10(6)(g) require that, unless expressly permitted, a food for sale must not be a *food produced using gene technology*, or have as an ingredient or component a *food produced using gene technology*.

LegH Prep meets the definition of *food produced using gene technology* (see subsection 1.1.2—2(3)), as it is derived from an organism modified using gene technology (i.e. derived from a GM *P. pastoris* strain).

In order to be permitted for use, express permission for soy leghemoglobin in the form of LegH Prep must be given in accordance with Standard 1.5.2 (i.e. the LegH Prep must be listed in Schedule 26 and comply with corresponding conditions listed in the Schedule).

1.3.1.2 Identity and purity

Section 1.1.1—15 requires that a substance used as a nutritive substance must comply with any relevant specification set out in Schedule 3 – *Identity and purity*. Soy leghemoglobin in the form of LegH Prep is intended as a new ingredient in Australia and New Zealand's food supply and since there are no specifications currently provided in the Code, a specification will be required in Schedule 3.

1.3.1.3 Labelling requirements

Subsection 1.1.1—10(8) requires that food for sale must comply with all relevant labelling requirements in the Code for that food.

Subsection 1.2.3—4(1) requires certain foods and substances to be declared when present as ingredients in a food for sale.

Standard 1.2.4 generally requires food for sale to be labelled with a statement of ingredients, subject to certain exemptions.

Standard 1.2.7 sets out the requirements and conditions for voluntary nutrition, health and related claims made about food.

Standard 1.2.8 sets out nutrition information requirements for food for sale, other than infant formula products and a Permitted Health Star Rating symbol.

Section 1.5.2—4 sets out labelling requirements for foods for sale that consist of, or have as an ingredient, food that is a *genetically modified food*. A *genetically modified food* is defined in subsection 1.5.2—4(5) as a *food produced using gene technology* that contains novel DNA or novel protein; or is listed in section S26—3 as being subject to a condition that its labelling must comply with section 1.5.2—4. The requirements set out in section 1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer[7] under paragraphs 1.2.1—8(1)(k) (food for sale required to bear a label), 1.2.1—9(3)(b) (food for sale not required to bear a label), and 1.2.1—15(f) (food sold to a caterer). The requirement to label food as 'genetically modified' does not apply to GM food intended for immediate

[7] 'Caterer' is defined as a person, establishment or institution (for example, a catering establishment, a restaurant, a canteen, a school, or a hospital) which handles or offers food for immediate consumption (subsection 1.1.2—2(3) of the Code. Consequently, in relation to such food, a consumer may seek information about the food from the food business.

consumption; and which is prepared and sold *from* food premises and vending vehicles, including restaurants, take away outlets, caterers, or self-catering institutions (paragraph 1.5.2—4(1)(e)).

For further discussion about labelling requirements in the Code that would apply to soy leghemoglobin (in the form of LegH Prep), see section 3.2 of this report.

1.3.2 International Regulations

1.3.2.1 Codex

Codex provides general guidance on safety assessment, but does not direct its members to specific regulatory approaches relevant to soy leghemoglobin. FSANZ follows this internationally recognised risk analysis framework to undertake the safety assessments for applications. For the purposes of assessing A1186 in relation to toxicology and GM safety, FSANZ has considered the following (respectively):

- The International Programme on Chemical Safety's Principles and Methods for the Risk Assessment of Chemicals in Food (FAO/WHO 2009). This guideline was developed by the the Joint FAO/WHO[8] Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), who serve as scientific advisory bodies to the Codex Alimentarius Commission.
- The FAO/WHO Codex Alimentarius provides guidance to members on internationally agreed GM food safety guidelines (Codex 2009).

1.3.2.2 United States

Impossible Foods obtained self-affirmed USFDA GRAS status (GRN 737) in July 2018 to use its soy leghemoglobin at levels up to 0.8% in its raw ground (minced) beef analogue products as a flavour optimiser. In addition, the applicant lodged a colour additive petition to the USFDA in response to their request in November 2018 to amend the colour additive regulations in 21 CFR part 73, 'Listing of Color Additives Exempt from Certification'. A risk assessment conducted by the USFDA as part of the colour additive petition concluded that there were no toxicological concerns regarding the proposed use of soy leghemoglobin in ground beef analogue products. This rule came into effect in 4 September 2019[9]. USFDA currently has also a policy statement that identifies fortification practices that manufacturers are encouraged to follow. However, this policy is guidance only, and USFDA employs labeling requirements rather than rigid standards for nutrient composition to assist consumers.

1.3.2.3 Canada

In January 2020, Impossible Foods received a letter of no objection on the use of soy leghemoglobin preparation (LegH Prep) from Health Canada for use in ground beef analogues at level up to 0.8% soy leghemoglobin.

1.3.2.4 Singapore

The Agri-Food and Veterinary Authority (now the Singapore Food Agency) in August 2018 permitted the applicant's soy leghemoglobin in 'plant-based meat analogues' at levels up to 0.45% (SFA 2019). FSANZ consulted with the SFA to discuss their assessment processes, and to understand why their permissions were for 0.45% instead of the 0.8% requested in application A1186. The SFA representatives indicated they undertook a risk analysis similar

[8] FAO is the Food and Agriculture Organization of the United Nations; WHO is the World Health Organization.
[9] https://www.regulations.gov/document?D=FDA-2018-C-4464-0002

to FSANZ, and that the level was permitted because Impossible Foods only applied to permit soy leghemoglobin at levels of 0.45%. SFA representatives confirmed that the applicant would have to apply for a higher level, if required.

1.3.2.5 Hong Kong and Macau

The applicant indicated that soy leghemoglobin was respectively permitted in Hong Kong and Macau following approvals in the US and Singapore. The applicant provided information that no regulatory provisions apply specifically to GM foods in Hong Kong and such foods are not distinguished from non-GM foods. The applicant also indicated that the Hong Kong Centre for Food Safety takes into account whether or not a safety evaluation has been conducted by international food safety authorities.

The applicant highlighted that most international imports, other than those from China, are transhipped to Macau via Hong Kong. Therefore food products that comply with Hong Kong's food regulations can generally be marketed in Macau.

1.3.2.6 European Union

Impossible Foods lodged a request in October 2019 to market soy leghemoglobin produced from genetically modified *Pichia pastoris* with the European Food Safety Authority (EFSA)[10] (Requestor member state – The Netherlands). At the time of writing, this application is currently under consideration as a GM food under Regulation (EC) 1829/2003.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application is being assessed under a Major Procedure.

2 Summary of the assessment

2.1 Summary of issues raised in submissions

At the 1st CFS, FSANZ received a total of 44 submissions from six key submitter groups (see Attachment D for a full list of submitters):

- State government (5)
- Industry (6)
- Not for profit organisations (4)
- Primary production organisations (3)
- Consumer organisations (10)
- Individual submitters (16)

These submissions have been published on the A1186 webpage. Across the different submitter groups, FSANZ noted mixed support for the application and FSANZ's safety and

[10] For further information see EFSA registration of questions webpage; Application number GMO-2019-0008; mandate number is M-2019-0132.

risk assessment.

Supporting submissions generally provided the following rationale:

- Impossible meat analogue products may provide a sustainable alternative option to meat products.
- Permitting soy leghemoglobin promotes greater choice for consumers wishing to reduce their meat intake.
- The FSANZ risk and technical assessment is supported by appropriate data and information to justify the safety of soy leghemoglobin in the form of LegH Prep.
- Soy leghemoglobin provides a bioavailable source of haem iron in meat analogue products (currently only non-haem iron is permitted in the Code where iron addition is permitted more generally).
- FSANZ's proposed permission promotes an innovative and internationally competitive industry.

Issues or questions requiring clarification from relevant submissions have been summarised and responded to in Table 1.

FSANZ noted a high volume of stakeholder interest in broader issues relating to the applicant's Impossible meat analogue products, and analogue products more broadly. Any issue pertaining directly to the final food for sale has been addressed in Table 2.

Table 1: Summary of issues with soy leghemoglobin in the form of LegH Prep

	Issue	Raised by (No. submitters)	FSANZ response
	Proposed regulatory approach of soy leghemoglobin in Australia and New Zealand		
1.	The purpose of soy leghemoglobin is unclear in the application and 1st CFS report, therefore FSANZ's proposed regulatory approach has not been made clear.	Not for Profit (1); Government (4)	FSANZ acknowledges submitter requests for clarity around the regulatory approach taken for soy leghemoglobin as the purpose of the 1st CFS was to present the safety assessment and present an initial regulatory direction. FSANZ has now finalised a proposed draft variation for the Code that explains the draft regulatory approach for soy leghemoglobin in the form of LegH Prep (see Attachment A). Additionally, the risk management consideration in support of FSANZ's proposed draft variation can be found under section 3 of this report.
2.	FSANZ's regulatory approach does not appear to align with that of other international agencies. One submitter requested FSANZ defer assessment of the application until the current EFSA assessment is finalised.	Government (3) Consumer organisation (1)	Aligning regulation of individual ingredients with overseas agencies is not always possible or appropriate. Codex provides general guidance on safety assessment, but does not direct its members to a specific regulatory approach. Each similar country has its own regulatory system that differs in several respects from Australia and New Zealand. For example, the USFDA does not regulate a category of nutritive substances. FSANZ must determine regulatory measures that are most applicable within the construct of the Code. As an independent statutory agency, FSANZ cannot delay the completion of an assessment based on current or future international permissions.
3.	Submitter queried the need for a maximum permitted use level for soy leghemoglobin. Given no public health and safety concerns were identified during the risk and technical assessment.	Industry (1)	FSANZ has determined it is appropriate to set a maximum permitted level for the reasons discussed in Section 3.1.1 *Permitted use levels of soy leghemoglobin*..
4.	What is the risk of the soy leghemoglobin being added to meat products (for example, to add colour and/or extend shelf life)?	Government (2)	Soy leghemoglobin is proprietary to the applicant. The use of soy leghemoglobin would be permitted in meat analogue products only, not other food categories. See Table 2, number 14.

	Issue	Raised by (No. submitters)	FSANZ response
5.	Clarify if '5g of protein per serve of the food' is a qualifying limit for 'analogues of meat' under S17—4 of the Code, or an upper limit.	Government (1)	FSANZ acknowledges that the wording '5g of protein per serve of the food' under S17—4 is unclear. FSANZ has drafted a 'consequential amendment' to '**no less than** 5g of protein per serve of the food' which was the original intention of this condition.
6.	The applicant's method of analysis for detecting soy leghemoglobin in meat analogue products has been provided as confidential information, concerns are that this may limit the Jurisdictions' capacity to monitor soy leghemoglobin.	Government (2)	FSANZ acknowledges this issue and has provided further information under Section 3.1.2 *Identifying levels of soy leghemoglobin in food*.
	Labelling of soy leghemoglobin as an ingredient		
7.	Concerned how the ingredient will be labelled (as 'soy leghemoglobin' or 'LegH Prep'), given that 'LegH Prep' does not indicate the presence of soy protein.	Government (1); Not for Profit (1)	Existing requirements for ingredient labelling and allergen declarations would apply (refer to Section 3.2.1 *Name of ingredient* and Section 3.2.2 *Mandatory declaration of certain foods or substances in foods*). The applicant has stated the common name of this ingredient is 'soy leghemoglobin' and that packaged food products would carry a 'soy' declaration.
8.	Concerned this ingredient will be present below the amount required for GM labelling to apply.	Consumer submitter (1)	If approved, soy leghemoglobin is an ingredient in a food for sale (refer to Section 3.2.3 *Labelling as 'genetically modified'*). This requirement is not subject to a certain threshold.
9.	Suggest an education campaign be undertaken to inform consumers of the nature of the ingredient and the role it plays in meat analogues.	Not for profit (1)	FSANZ considers existing Code requirements for allergen declarations, ingredient labelling and for labelling of GM foods will apply to the ingredient which will provide information for consumers to make informed, safe choices.
	Safety and Technical data – GM assessment		
	Several submissions relating to the GM assessment were received. No new or substantive scientific evidence was provided that would change the conclusions of FSANZ's evaluation of the safety of soy leghemoglobin in the form of LegH Prep.		
10.	Soy leghemoglobin and the endogenous *Pichia pastoris* proteins have not been in the Australian and New Zealand food supply before and the	Primary production organisation (2); Not for profit (1);	The approach used by FSANZ to assess the safety of a GM food is based on core principles established by the Codex Alimentarius Commission (Codex 2009). This approach includes protocols to assess the potential allergenicity and

	Issue	Raised by (No. submitters)	FSANZ response
	safety assessment has not been adequate to address these issues.	Individual submitters (10); Consumer organisations (6); Government (2)	toxicity of new proteins. Since 2003, the assessment protocol adopted by Codex has been subject to scientific scrutiny and has proven to be a robust approach for food safety assessments. Thus it has been widely adopted and implemented around the world. FSANZ applied this approach, particularly for the assessment of new proteins, to the assessment of the LegH Prep. Consumers can be confident that GM foods assessed under the protocol and approved for food use are safe. **Safety of Pichia proteins** FSANZ acknowledges there is no evidence of human consumption of proteins from *Pichia* pastoris. The strain of *Pichia* used in this application has been fully characterised at the molecular level and there is no evidence of genes encoding toxic proteins or other toxin production. The animal feeding and genotoxicity studies provided by the applicant demonstrate that the *Pichia* proteins present in the LegH Prep do not cause adverse effects. Studies involving feeding viable *Pichia pastoris* to chicken and mice also show no evidence of adverse effects. **Approach used to address potential allergenicity and toxicity** FSANZ undertook an independent assessment of the novel proteins and concluded there were no safety concerns regarding potential allergenicity or toxicity of soy leghemoglobin or the *Pichia* proteins This assessment included: bioinformatic analyses comparing the amino acid sequences of soy leghemoglobin and the identified Pichia proteins to databases with known allergens and toxins (*in silico*); physicochemical assays that model cooking (thermal stability) and the digestive system processes (stability to acid and digestive enzymes); and acute animal toxicity studies. For soy leghemoglobin and many of the endogenous *Pichia* proteins, there was a degree of similarity to a number of cellular housekeeping proteins that are associated with toxins or allergens but which are not themselves toxins or allergens. These proteins are constitutively expressed at high levels and are involved in major metabolic or cell synthesis pathways. As these proteins are required by all cells, the sequences of these proteins are highly conserved across kingdoms and phyla. Many of the proteins in question had higher sequence similarity to proteins found in common foods or microbes used in food, where there is no evidence of adverse effects.

	Issue	Raised by (No. submitters)	FSANZ response
			Many of the proteins shared sequence similarity to the same proteins found in toxigenic yeast and bacteria. None of the proteins in question have been shown to be allergenic or toxigenic. Furthermore, the proteins in question were part of the preparation used in the animal feeding study. None of the animals exhibited adverse effects associated with the test article (the soy leghemoglobin preparation, containing the endogenous *Pichia* proteins), confirming the bioinformatics results and literature review. **Literature review** FSANZ also undertook a literature search to confirm the absence of evidence of either toxicity or allergenicity associated with the novel proteins. **Data provided to FSANZ** The data provided to FSANZ was generated by the applicant and contract laboratories. The data requirements of the studies are outlined in the FSANZ Application Handbook, and are based on protocols established by Codex and the OECD. For example, the toxicity studies were conducted by contract research laboratories in compliance with OECD test guidelines and Good Laboratory Practice standards. This means that significant and robust quality control measures were applied to them by the study director and independent auditors. FSANZ independently reviewed the quality of the studies and all of the data including raw data, and considered them suitable for regulatory purposes.
11.	FSANZ has only used safety assessment data from one strain (MXY0291). Evidence shows different *Pichia pastoris* proteins are expressed across strains and batches, which could impact safety and purity.	Government (2), Consumer organisations (2); Primary production organisation (1)	In the development of a *Pichia pastoris* strain expressing soy leghemoglobin, the applicant has generated two strains for production purposes. Both strains express the same leghemoglobin protein, containing an iron-bound heme component. Molecular and physicochemical data was provided for the total LegH Prep product from both strains and was highly comparable. The purity and specification for the product has been based on batch analyses from both strains. In the specifications, protein makes up 14% of the total LegH Prep with soy leghemoglobin making up > 65% total protein. Detailed analyses identified the most highly expressed *Pichia* proteins across both strains and fermentation cultures. There were many common proteins

	Issue	Raised by (No. submitters)	FSANZ response
			across strains and cultures because these endogenous proteins are constitutively expressed to high levels. Both the soy leghemoglobin and *Pichia* proteins were shown to have no biologically significant similarity to known toxins or allergens, were fully degraded in heat and acid stability and proteolysis assays. Furthermore, it is important to note that a wide range of proteins exist in the human diet of which the vast majority are neither toxigenic nor allergenic. While the animal studies were performed using the LegH Prep from one strain, both strains met the specifications provided by the applicant and were shown to contain a similar mixture of *Pichia* proteins. The results from the toxicity assay indicated there were no adverse effects from either the soy leghemoglobin or *Pichia* proteins. Other agencies have also performed a full safety assessment that supports FSANZ's conclusion: Health Canada, Singapore, US FDA.
12.	Does FSANZ consider whether peptide fragments of the soy LegH protein may be biologically active in Coeliac disease, gluten-intolerant or soy allergic individuals?	Individual Submitter (1); Not for profit (1)	If the gene encoding the new protein is sourced from a known gluten source (wheat, barley, oats etc), FSANZ requires investigation into the role of that protein in elicitation of gluten-sensitive enteropathy. This requirement is specified in the Application Handbook, in Guideline 3.5.1 Foods produced using gene technology (Section B.2 (b) (v)). As the soy leghemoglobin gene is not sourced from a gluten-containing cereal grain, there was no requirement to undertake this assessment. General allergenicity concerns are addressed according to the internationally accepted Codex approach: 1) bioinformatics (*in silico*) to compare similarity to known allergens; 2) physicochemical assays that model cooking and the digestive system processes; 3) if there is evidence of similarity to known allergens or minimal protein denaturation and/or digestion, serum screening studies would be required. As the proteins present in the LegH Prep showed no biologically significant similarity to known allergens and were fully denatured and digested, there was no requirement to undertake further assessment. For information about labelling, refer to FSANZ's response to issue 7 above, relating to soy declarations.
13.	Suggested consulting a scientific committee that	Not for profit (2)	FSANZ has access to external experts, in particular the Food Allergy and

	Issue	Raised by (No. submitters)	FSANZ response
	provides expert knowledge on allergic disease		Intolerance Scientific Advisory Group. In regard to this application, analysis of the data did not raise concerns regarding allergenicity, therefore the scientific advisory group was not consulted. Additionally, post-market surveillance data provided by international regulatory partners has not identified any confirmed adverse events following consumption of meat analogue products containing soy leghemoglobin. This is consistent with data provided by the applicant and the outcomes of FSANZ's safety assessment.
14.	The USFDA has said that, "Conformational similarity or functional similarity among proteins is not an indication of the safety of proteins for consumption." Dr Michael Hansen, senior scientist with Consumers Union and member of the GMOScience Advisory Board, agreed, "just because proteins have similar functions or similar three-dimensional structures, doesn't mean that they're similar. They can have a very different amino acid sequence, and just slight changes can have impacts." Such impacts could include unexpected toxicity or allergenicity.	Consumer organisation (1)	FSANZ did not base its safety assessment only on structural or sequence similarity but rather considered the totality of the evidence, which in this case consisted of a full molecular characterisation, assessment of physicochemical properties, toxicology, nutritional and dietary intake assessment. After considering all the evidence FSANZ concluded there are no public health and safety concerns associated with the use of LegH Prep in meat analogue products at the proposed levels.
15.	FSANZ has not considered herbicide use for the genetically modified soy protein component of Impossible Burgers	Consumer organisation (3)	In the assessment of the LegH Prep, there was no requirement to assess the herbicide use in the potential meat-analogue products that may contain LegH. The LegH Prep is produced by a fermentation process, where herbicides are not used. If a protein concentrate to be used in the meat analogue products is sourced from herbicide-tolerant soybean, whether non-genetically modified or genetically modified, the Code already mandates maximum residue limits of Agvet chemicals, including herbicides, through Standard 1.4.2. Furthermore, if the applicant sources the protein component from a genetically-modified soybean in the products for sale in Australia and New Zealand, they can only use soybean products approved by FSANZ and listed in Schedule 26.

	Issue	Raised by (No. submitters)	FSANZ response
	Safety and Technical data – Toxicology assessment		
	Several submissions relating to the toxicology assessment were received. No new or substantive scientific evidence was provided that would change the conclusions of FSANZ's evaluation of the safety of soy leghemoglobin.		
16.	Rats in the feeding study showed statistically significant changes in some measures. Why were these considered of 'no toxicological relevance'?	Primary production organisation (1); Consumer organisation (2) Individual submitters (2)	Statistically significant changes are frequently observed in toxicity studies but these do not necessarily represent test article-related effects. Such changes may be due to normal variability between individual animals. Considerations that are taken into account in determining whether differences between control and treated groups are due to the test article, and whether such differences are adverse, include the magnitude of change, whether effects show a dose-response, consistency over time and between sexes, correlation with clinical observations, correlation with other clinical pathology and histopathologic observations and comparison with historical control ranges. In the case of the statistically significant differences observed in the 28-day study with LegH Prep, these were not considered to be treatment-related as they were of a small magnitude, did not show a dose-response, were only seen in one sex and were not accompanied by other correlated pathological changes.
17.	The feeding studies do not reflect human consumption patterns, involve small sample numbers and are of too short a duration.	Government (1); Primary production organisation (1); Consumer organisations (4)	In the toxicity studies with LegH Prep, the test substance was administered as part of the animals' diet. This method of administration is standard practice in oral toxicity studies and is considered representative of dietary exposure to LegH Prep from food. With respect to sample sizes, in the 14-day study 6 males and 6 females were used at each dose level, while in the 28-day study 10 males and 10 females were used at each dose. In the investigative 28-day study in female rats, 15 animals were used per dose groups. These numbers are all higher than those recommended in the OECD Test Guideline for 28-day toxicity studies (5/sex/group) and therefore considered to be adequate. Proteins known to be toxic to mammals generally cause acute toxicity, so further testing of LegH Prep in a 90-day study would not be justified given it is rapidly

	Issue	Raised by (No. submitters)	FSANZ response
			digested and showed no toxicity in the 28-day study.
18.	Séralini's animal studies showing concerning results of glyphosate exposure has been criticised and dismissed. Why has FSANZ accepted the studies on soy leghemoglobin without similar criticisms?	Individual submitter (1)	The Séralini study (Séralini et al. 2012 RETRACTED) had a number of methodological limitations, outlined in the FSANZ *Response to studies cited as evidence of adverse effects from GM foods*[11]. When the appropriate methods were used, the results obtained by Séralini were not replicated (Coumoul et al. 2019; Steinberg et al. 2019), further indicating the limitations of the results obtaining in the Séralini study. The studies provided to FSANZ for LegH Prep were conducted using accepted methodologies, in accordance with principles of Good Laboratory Practice and in accordance with internationally accepted OECD Test Guidelines. FSANZ also independently reviewed the quality of the studies and considers them suitable for regulatory purposes.
19.	Why has FSANZ not required an assessment of the estrogenic properties of soy-based products in the toxicology data?	Consumer organisations (2); Individual Submitters (TBC)	The 28-day toxicity study was conducted in accordance with OECD Test Guideline 407, which was updated in 2008 to include endpoints for the detection of endocrine disruptors. No adverse effects on these endpoints were found, indicating a lack of endocrine disrupting properties, including estrogenic effects.
20.	Why has FSANZ not acknowledged the adverse effects on humans, reported after eating the Impossible Burger?	Consumer organisations (2); Individual submitter (1)	One submitter referred to a Science in the News Article from Harvard University entitled *Will GMOs hurt my body?*. This article acknowledges there are fears about GM foods but concludes that there is no evidence from over 100 research studies that GM foods cause harm. Submitters also provided links to social media websites, where individuals have made statements regarding adverse reactions after eating an Impossible Burger. a) Vegan group hosted on Reddit. b) A US Food Poisoning platform FSANZ is aware of online reports of adverse effects following consumption of burgers containing soy leghemoglobin. These self-reports are anecdotal in nature and have not been subject to independent medical verification as far as

[11] www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx

	Issue	Raised by (No. submitters)	FSANZ response
			FSANZ is aware. The effects reported are generally non-specific gastrointestinal symptoms that are not clearly attributable to soy leghemoglobin or the Impossible Burger, as individuals will have consumed other food items at the same time as well as in the preceding hours or days. The time of onset of food-borne illness may be several hours or days following consumption, adding to the difficulty in attributing a cause to a case of illness. As of March 2020, the applicant advised they had sold approximately 100,000,000 quarter-pound (113 g) servings of meat analogue products containing soy leghemoglobin. Its post-marketing surveillance identified 1 complaint of a potential adverse event per 100,000 quarter-pound (113 g) servings of the Impossible Burger from the previous wheat-based formulation of the burger. With the current recipe (released early 2019) the rate of complaints has been 1 per 600,000 servings. None of these complaints has been confirmed as an adverse event due to consumption of these products, however. FSANZ considers that the available evidence does not indicate a significant public health concern from consumption of soy leghemoglobin at the proposed levels.
21.	Please clarify if adverse effects reported for the Impossible Burger may be related to interaction between the soy leghemoglobin ingredient and soy lectins in the burger, which could make a poisonous compound.	Private submission (1)	The submitter suggested that soy leghemoglobin may bind to soy lectins, leading to the formation of a large indigestible complex, which could be potentially poisonous. No evidence was provided to support this claim. FSANZ conducted a literature search and has not identified any evidence that suggests a food matrix would modify the structure, function, or safety of soy leghemoglobin under its proposed use conditions.

	Issue	Raised by (No. submitters)	FSANZ response
22.	FSANZ could elaborate on why the Margins of Exposure (MOE) are acceptable by confirming the highest dose level and the associated No Observed Adverse Effects Level (NOAEL) used in the toxicology studies were the highest levels consistent with palatability and nutritional balance of test diets, if this were the case.	Government (1)	The highest dose used in the toxicity studies was not selected based on palatability or nutritional balance but because it was more than 100 times greater than the 90th percentile estimated daily intake of LegH Prep in ground beef analogue products, as estimated by the Applicant. FSANZ's estimate of dietary intake of LegH Prep was higher than that calculated by the Applicant, resulting in MOEs smaller than 100. However, as agreed by the submitter, the MOEs are not considered to be of concern given that a sufficient body of knowledge exists on the safety of the source organism, and the proteins in LegH Prep will be digested like other dietary proteins and do not share any significant similarities to known allergens or toxins. In addition, the conservative nature of FSANZ's dietary intake assessment is likely to overestimate intakes over a long period of time or a lifetime. The assessment assumes that products containing LegH Prep will be consumed frequently over a long period of time, in the same amounts that the Australian and New Zealand populations currently consume minced meat and poultry products and existing vegetarian meat alternatives. It also assumes that all meat analogue products on the market would contain LegH Prep. It is unlikely that products containing LegH Prep, if approved, would be consumed frequently over a long period of time, or that 100% of meat analogue products consumed would contain LegH Prep.
23.	Some research suggests that haem iron may contribute to an increased risk of colon cancer and other health problems that have been associated with red meat consumption. It's still unknown whether the haem iron from soy leghemoglobin may pose that same risk: https://www.ncbi.nlm.nih.gov/pubmed/25592152	Consumer organisation (1);	While the International Agency for Research on Cancer (IARC) has classified red meat as probably carcinogenic to humans, the reasons for such an association are not yet fully understood. Red meat contains a number of substances in addition to haem iron that have been suggested to be potential contributors, including heterocyclic amines and polycyclic aromatic hydrocarbons formed during cooking. IARC has noted that the potential carcinogenic mechanisms associated with consumption of red meat cannot be attributed to a particular meat component (IARC 2018). Recent reviews of studies conducted with haem to investigate a potential carcinogenic mechanism have concluded that these studies have a number of limitations, and there is insufficient evidence to confirm a mechanistic link between consumption of haem iron and an increased risk of colorectal cancer

	Issue	Raised by (No. submitters)	FSANZ response
			(Kruger and Zhou 2018; Turner and Lloyd 2017). In addition, there is no evidence available indicating that the dietary intake of haem from soy leghemoglobin would contribute to an increased risk of cancer. The available studies with soy leghemoglobin found that it was not genotoxic, and the repeated dose toxicity studies found no evidence of lesions that could lead to neoplasia through non-genotoxic mechanisms.
	Safety and Technical data – Nutritional impact assessment		
24.	If the absence of meat proteins in the final product may decrease haem iron bioavailability of soy leghemoglobin, then it is not accurate to state that the final product has similar nutrition characteristics as meat.	Consumer organisation (1)	FSANZ considers that haem iron from soy leghemoglobin is likely to have similar bioavailability to haem iron from meat haemoglobins. Soy leghemoglobin has a similar structure and physicochemical properties to animal myoglobins, contains the same haem B prosthetic group that is released in the acidic environment of the stomach, and denatures at a lower temperature than equine myoglobin. Further evidence was provided by an vitro study in which iron from soy leghemoglobin showed similar bioavailability to iron from bovine haemoglobin. FSANZ notes that the bioavailability of haem iron from soy leghemoglobin may be reduced due to the absence of meat proteins in the final product. However, as described in SD1, the total iron content of the proposed meat analogue products is higher than comparison meat products, thereby compensating for any potential decrease in bioavailability. In addition, iron absorption is tightly regulated by the body, increasing when individuals are iron deficient and decreasing when iron overload occurs. Therefore, FSANZ considers that in terms of iron bioavailability a nutritional disadvantage would not result from consumption of these products. Further consideration of the nutritional value of the meat analogue product is out of scope.
25.	FSANZ has 'cherry picked' evidence in considering iron in isolation from soy leghemoglobin and not within the food matrix. This includes how other ingredients/nutrients are made or interact together.	Primary production organisation (1); Consumer organisation (2)	FSANZ describes in SD1 various factors that can influence iron absorption, including the effects of interactions between iron and other food components, and the broad ranges reported in the literature for the bioavailability of dietary haem and non-haem iron.

	Issue	Raised by (No. submitters)	FSANZ response
	Dietary Intake Assessment		
26.	NZ survey data upon which FSANZ based its DIA is outdated and therefore not representative of current diets. Modelling should more accurately reflect actual intake of these products.	Primary production organisation (1)	FSANZ acknowledges that the most recent national nutrition survey (NNS) data for Australia and New Zealand is not current. However these are the best data sets available to FSANZ for quantifying dietary intake at present. The estimated intakes of LegH Prep and iron assume that individuals will consume meat analogue products containing LegH Prep in the same amounts they consume minced meat and poultry, and vegetarian meat alternatives, as reported in the latest NNS. These foods best reflect the ways in which foods containing soy leghemoglobin in the form of LegH Prep (if permitted) could be consumed, for example as burger patties, sausages and in place of minced meat in mixed foods. In addition, the modelling takes into account the range of consumption amounts reported within the population, so includes people who have consumption amounts of meat analogues containing soy leghemoglobin equivalent to eating a burger containing either one or two patties. A comparison of the results from the Australian NNSs from 1983,1985 and 1995 showed the consumption of dietary staples, including meat and poultry, remains fairly constant over time (Cook, Rutishauser & Allsopp, 2001; Cook, Rutishauser & Seelig, 2001). This is also likely to be the case for staples in the New Zealand diet.
27.	Provisions need to be put in place to ensure safety of under 2 years of age	Primary production organisation (1)	The toxicological assessment did not identify any population sub-groups for which there were specific safety considerations. Therefore the dietary intake assessment was conducted for the general Australian and New Zealand populations for which national nutrition survey data is available (2 years and over for Australia, 5 years and over for New Zealand). The dietary intake assessment estimates intake of LegH Prep and iron over a long period of time or lifetime, reflecting chronic dietary intake.
28.	Consideration needs to be given to cooked product and iron composition because iron	Primary production organisation (1)	FSANZ's dietary intake assessment takes into account that the Leg H Prep added to the raw product, and the iron it contributes would further concentrate

	Issue	Raised by (No. submitters)	FSANZ response
	increases after cooking		where moisture loss occurs during cooking. The range of meat analogue products that would contain LegH Prep, should the permission be approved, is unknown. Therefore it was assumed for the assessment that the moisture loss from cooking meat analogue products containing LegH Prep is equivalent to the moisture loss from cooking the minced meat and poultry or vegetarian meat alternatives when deriving the consumption amounts.

Table 2: Summary of issues with the final meat analogue product for sale

	Issue	Raised by (No. submitters)	FSANZ response
	Labelling of the final meat analogue products for sale		
1.	Sought clarification that soy declaration requirements will apply to meat analogue products containing soy leghemoglobin.	Government (1); Not for Profit (2); Primary production organisation (1)	Existing requirements for the declaration of soy would apply to packaged and unpackaged meat analogue products. The addition of soy leghemoglobin as an ingredient would trigger a soy declaration (refer to Section 3.2.2 *Mandatory declaration of certain foods or substances in foods*).
2.	The 1st CFS notes a voluntary representation to make 'good source' claims for iron, however the supporting evidence does not demonstrate the bioavailability of iron from this food source.	Government (1)	Nutrition content claims refer to the presence or absence of nutrients and can also refer to amounts present. Bioavailability is not a consideration for nutrition content claims as it is influenced by many factors. Bioavailability of haem iron from soy leghemoglobin is discussed in Table 1 (issues 24 and 25).

	Issue	Raised by (No. submitters)	FSANZ response
3.	Clarity is sought on what health claim restrictions will apply to this food, and if the proposed iron content of the applicant's meat analogue products would permit a 'general level health claim'.	Government (1); Primary production organisation (1)	Existing requirements for nutrition content and health claims would apply to meat analogue products containing soy leghemoglobin. Section S4—5 of the Code includes certain pre-approved general level health claims about iron that may be used if conditions are met, including a minimum content of iron. Standard 1.2.7 requires a systematic review to substantiate any food-health relationship not listed in section S4—5 (refer to Section 3.2.5 *Nutrition content and health claims*). The onus is on the supplier to ensure the conditions for such claims are met.
4.	Clarity is requested on how voluntary %RDI claims for vitamins and minerals in S17—4 would be applied for the applicant's products containing soy leghemoglobin, including if 'good source of iron' claims apply.	Government (1)	A voluntary %RDI claim can be made for vitamins and minerals listed in section S17—4, up to and including the maximum claimable amount for that vitamin or mineral (when one is provided). However, the actual amount of the vitamin or mineral present in a serving of the food may exceed the maximum claimable amount for a %RDI declaration, subject to all conditions being met and where the maximum permitted amount (if any) is not exceeded. In relation to meat analogues, there are no maximum permitted amounts per reference quantity for iron and zinc (refer to Section 3.2.5.1 *Restrictions on nutrition content claims in relation to vitamins and minerals added to foods* for requirements for %RDI claims).
5.	Sought clarification that the 'genetically modified' statement will apply to commercial meat analogue products containing GM soy leghemoglobin.	Primary production organisation (1); Consumer organisation (1)	Existing Code requirements for genetically modified food would apply. The 'genetically modified' statement would be required if soy leghemoglobin is an ingredient in a packaged meat analogue product for sale (refer to Section 3.2.3 *Labelling as 'genetically modified'*).
6.	Meat analogues made with soy leghemoglobin and sold from restaurants, takeaway outlets or by caterers should be labelled as 'genetically modified'.	Consumer organisation (1); Individual submitters (8)	The existing exemption from GM labelling for all GM food and ingredients sold for immediate consumption has been in effect since 2002. This approach was reaffirmed in the 2011 Government response to recommendations made in Labelling Logic: Review of Food Labelling Law and Policy. See Section 3.2.3 *Labelling as 'genetically modified* for existing labelling requirements, which states that consumers may seek information about the food from the food business.
7.	Concerned the applicants' meat analogue	Government (1);	The Code requires a name that is sufficient to indicate the true nature of the

	Issue	Raised by (No. submitters)	FSANZ response
	products would be represented as meat products and requested clear labelling for consumers to make informed choices. Requested FSANZ consult with the ACCC regarding the naming and marketing of Impossible products containing soy leghemoglobin.	Primary production organisations (2); Consumer organisations (2); Individual submitters (6)	food. If a particular food is defined for compositional purposes (e.g. 'sausage'), the Code allows the name of a food to be further qualified so the context makes it clear the food for sale is not the food as defined (e.g. 'soy sausage'). FSANZ reviewed the evidence about consumer trends in meat consumption and their understanding of meat analogue products (refer to Section 3.2.6 *Representations*). FSANZ has also discussed the marketing of meat analogue products with the Australian Competition and Consumer Commission (ACCC) and New Zealand Commerce Commission (NZCC). These agencies are responsible for administering consumer protection legislation which prohibits misleading or deceptive conduct and false or misleading representations about goods and services. Their advice regarding consumer protection legislation and the complaints they have received to date is described in the same section.
8.	Concerned that meat analogue products are processed foods and should not claim nutritional equivalence to meat. The applicants' meat analogue products should be labelled with the statement 'not a dietary substitute for meat'.	Government (1); Primary production organisations (2); Consumer organisation (1) Individual submitters (6)	Voluntary nutrition content claims may be made about these products if claim conditions are met, and claims that compare vitamin or mineral content of one food with another food are prohibited. FSANZ considers the suggested statement would be inappropriate because meat analogue products are dietary substitutes for meat (refer to Section 3.2.6.3 *Nutritional equivalence of meat analogue products to meat*).
9.	Environmental and ethical claims made by the applicant about their meat analogue product have not been substantiated.	Primary production organisation (1)	The Code does not include requirements for environmental or ethical claims. This is because the standards within the Code are principally aimed at protecting public health and safety (e.g. a standard that requires mandatory declarations for food allergens). When provided voluntarily on food labels, these types of representations are subject to consumer protection legislation which prohibit false, misleading or deceptive conduct.
	Other issues on the final meat analogue products for sale		
	Why has FSANZ not assessed the final Impossible meat analogue products for sale?	Consumer organisation (2)	Manufacturers have a responsibility to ensure all ingredients in their products sold in Australia and New Zealand comply with the Code. Application A1186 requests to introduce soy leghemoglobin only, a GM nutritive substance, into

	Issue	Raised by (No. submitters)	FSANZ response
			meat analogue products. It has no history of safe use in Australia or New Zealand, for this reason FSANZ has a legislative requirement to assess its safety and suitability for human consumption.
11.	What quality control processes are in place to ensure the safe production of Impossible products containing soy leghemoglobin?	Government (3)	The applicant has a requirement to ensure their manufacturing methods comply with Good Manufacturing Processes. They have provided the following information on their quality control processes: • They operate under the Hazard Analysis and Critical Control Point (HACCP) system which controls bacterial pathogens. • They have undertaken a biological assessment under Preventive Control regulations in the United States. • Certificates of Analysis (provided to FSANZ confidentially) for the final product confirms the absence of bacterial pathogens in the final frozen and packaged product. • Their facilities utilise dedicated production lines, employees and tools for meat analogue products. These control processes also include safe handling and storage of the final product for sale. • The quality assurance department inspect current co-manufacturing companies in the US and their adherence to contractual obligations. Any co-manufacturers are required to comply with third-party food safety requirements, such as The Safe Quality Food Institute's (SQFI) SQF Code in the United States and are required to pass third-party audits. • The traceability of soy leghemoglobin (in LegH Prep) production and distribution, removes the risk of unauthorised use.
12.	What is the likelihood of Impossible products cross-contaminating other products (such as meat)?	Government (2)	FSANZ considers the inadvertent addition of Impossible products to other food products (such as meat) highly unlikely. As mentioned above, FSANZ consider adequate control processes are in place to prevent this from occurring. If a co-manufacturer were to produce meat products in the same facility as Impossible products, the applicant would implement contracts requiring their products be produced on dedicated lines, with dedicated employees and tools. As discussed in the cost benefit Section of the 2nd CFS report, Impossible products are more expensive than meat, meaning there would be no incentive to

	Issue	Raised by (No. submitters)	FSANZ response
			mix this product with meat. Any third party misrepresenting the foods they sell are in breach of consumer laws.
13.	To ensure food safety, appropriate storage and preparation instructions of the applicant's meat analogue products should be provided to suppliers and consumers	Government (2)	Retail packaging for Impossible products in the US (available on google images) includes preparation instructions stating, "fully cooked when interior is 160°F" (71°C). The same instructions would be appropriate to include on packaging if the products were sold in Australia and New Zealand. The Code requires directions for use if the food must be used or stored in accordance with certain directions for health or safety reasons (subsection 1.2.6—2(b) of Standard 1.2.6 *Information requirements – directions for use and storage*). Furthermore, instructions will be provided to caterers and quick-service restaurants on safe handling and preparation of Impossible products. FSANZ has considered data and information on the applicant's food safety assessment that involved testing thawing, storage and cooking conditions of Impossible products. No observable food safety concerns have been identified.
14.	The scope of the cost benefit is too narrow (only on the soy leghemoglobin and not the applicant's final meat analogue product)		In the 1st CFS report, Section 5.1.1 *Consideration of costs and benefits* did consider costs and benefits of permitting soy leghemoglobin in the applicant's meat analogue products for sale, in addition to soy leghemoglobin as an ingredient.

2.2 Risk assessment

FSANZ conducted a comprehensive assessment consistent with the internationally recognised risk analysis framework based on a weight of evidence approach, combining information and scientific evidence provided by the applicant with independent sources (see SD1 – Risk and technical assessment report).

2.2.1 Safety assessment

The toxicological assessment was conducted consistent with internationally agreed practices and processes set out in the International Programme on Chemical Safety's Principles and Methods for the Risk Assessment of Chemicals in Food (FAO/WHO 2009). This guidance establishes common practices for food regulators and is applied by the pre-eminent FAO/WHO food toxicology committees including the Joint FAO/WHO Expert Committee on Food Additives and Joint FAO/WHO Meeting on Pesticide Residues. Similarly, the safety assessment of the food produced by gene technology was undertaken according to the internationally agreed GM food safety guidelines established by FAO/WHO Codex (Codex 2009).

In conducting the risk assessment of the soy leghemoglobin and the LegH Prep, a number of criteria have been addressed, including the safety of the *P. pastoris* host strain, novel proteins, toxicity of the LegH Prep and a nutritional and dietary intake assessment. The safety assessment of the source organism and novel proteins concluded there were no public health and safety concerns. The source organism is a well characterised yeast with a recognised safe history of use for the production of food enzymes. It is neither pathogenic nor toxigenic.

The novel soy leghemoglobin was shown to be equivalent to that expressed in soybean and was shown to be expressed as a holoprotein. Analyses of the potential allergenicity or toxicity of all the novel proteins, including soy leghemoglobin and the *Pichia* proteins, did not identify any significant similarities to known allergens or toxins. The proteins were shown to be susceptible to pepsin digestion and were denatured at standard cooking temperatures and in acidic conditions that mimic the stomach environment. The shelf life and specifications of the LegH Prep are also appropriate for addition to meat analogue products.

The applicant submitted *in vitro* genotoxicity studies in bacterial and mammalian cells and an oral toxicity study in rats. These studies are intended to confirm the outcome of the compositional and bioinformatic analysis conducted as a part of the safety assessment. No hazard was identified in the submitted studies. LegH Prep was not genotoxic *in vitro* and did not cause adverse effects in short-term toxicity studies in rats. The NOAEL of freeze-dried LegH Prep in a 28-day dietary toxicity study in rats was 1536 mg/kg bw/day, the highest dose tested. This dose corresponds to 1421 mg/kg bw/day total organic solids (TOS).

Mean and P90 estimated dietary intakes of LegH Prep at the maximum proposed use level were 20 – 60 mg/kg bw/day TOS and 45 – 124 mg/kg bw/day TOS, respectively. Mean and P90 estimated dietary intakes of LegH Prep at the likely use level were 11 – 32 mg/kg bw/day TOS and 24 – 68 mg/kg bw/day TOS, respectively. The estimated intakes of LegH Prep for both scenarios are considered to be conservative and over-estimate exposure as it is unlikely that consumers will eat meat analogue products containing soy leghemoglobin in the same amounts or with the same frequency as they currently consume minced meat and poultry products, and vegetarian meat alternatives (particularly over a long period of time).

The margins of exposure (MOEs) between the NOAEL of 1421 mg/kg bw/day TOS in the rat oral toxicity study and estimated dietary exposures at the maximum proposed use level

ranged between 20 – 70 for mean exposures and between 10 – 30 at the 90th percentile. At likely use levels, MOEs for mean and P90 estimated dietary intakes ranged between 40 – 130 and 20 – 60, respectively. These MOEs are not considered to be of concern given that: a sufficient body of knowledge exists on the safety of the organism (it is not pathogenic or toxigenic); the proteins in LegH Prep will be digested like other dietary proteins and do not share any significant similarities to known allergens or toxins; and the conservative nature of the dietary exposure assessment which is likely to overestimate intakes over a long period of time.

2.2.2 Nutrition assessment

The nutrition assessment concluded that haem iron from soy leghemoglobin is likely to have similar bioavailability to haem iron from mammalian haem proteins (e.g. myoglobin present in muscle tissue). The absence of meat proteins in the proposed meat analogue products may decrease the bioavailability of haem iron from soy leghemoglobin. However, as iron absorption is regulated tightly by the body, and meat analogue products have higher total iron content due to higher content of non-haem iron relative to comparison foods, any decrease in haem iron bioavailability should not result in a nutritional disadvantage to consumers in Australia and New Zealand.

The estimated intakes of iron (with the additional iron contribution from soy leghemoglobin) for all population age/sex groups assessed for both the Australian and New Zealand populations are below the ULs for iron. The estimated iron intakes in FSANZs assessment, for both the *maximum proposed use level* and *likely use level* scenarios, are considered to be conservative and an overestimation of actual iron intakes. It is unlikely that consumption of meat analogue products containing soy leghemoglobin would pose a risk of iron exceedance to the Australian and New Zealand populations, including at levels up to 0.8% soy leghemoglobin.

As of March 2020, the applicant advised they had sold approximately 100,000,000 quarter-pound (113 g) servings of meat analogue products containing soy leghemoglobin. Its post-marketing surveillance has identified one complaint per 600,000 servings based on the current formulation (released on the market in the US in early 2019), but none of these complaints has been confirmed as an adverse event due to consumption of these products.

In conclusion, the assessment of soy leghemoglobin and the LegH Prep raises no public health and safety concerns associated with its use in meat analogue products at the proposed maximum level of 0.8% soy leghemoglobin.

3 Risk management

3.1 Regulation of soy leghemoglobin in the Code

FSANZ assessed soy leghemoglobin in the form of LegH Prep as a food produced using gene technology, due to its production method. FSANZ did not assess soy leghemoglobin in form of LegH Prep as a novel food because the GM and nutritive substance permissions more accurately reflect the nature of this ingredient (produced through microbial fermentation of a GM yeast) and the purpose for which it is being added to meat analogue products (as a source of iron).

FSANZ has also assessed soy leghemoglobin as a nutritive substance for the purpose of providing a source of iron to meat analogue products. This in turn enabled an assessment of the bioavailability of iron in soy leghemoglobin in fulfilling a nutritive purpose. FSANZ understands that the addition of soy leghemoglobin can also provide a flavouring and colouring effect, similar to that of myoglobin. FSANZ recognises that many substances

added to food may also impart flavour and/or colour. Several substances in the Code perform more than one function without being regulated as such. For example, several vitamins may also act as antioxidants or colorants. Equally, several food additives such as calcium salts contribute to the calcium content of food that may be declared in nutrition labelling.

3.1.1 Permitted use levels of soy leghemoglobin

FSANZ has proposed a maximum permitted use level of up to 0.8% soy leghemoglobin in raw product for the following reasons:

- There is an absence of safety data and information for soy leghemoglobin levels above 0.8%.
- Maximum use levels are usually set higher than intended use levels to allow for variability from batch to batch.
- The application indicates palatability starts to be adversely affected at levels beyond 0.8% soy leghemoglobin. Specifically, this relates to the haem iron in the soy leghemoglobin leading to 'livery' or 'metallic' flavours that are off-putting at higher levels.
- This level aligns with the lower end of the range of myoglobin content in red meat (0.8 – 1.8%) (Texas A&M Institute, 2019).

FSANZ has not proposed to establish a minimum permitted use level because soy leghemoglobin is proposed as a permitted form of haem iron while relying on the Code's existing criteria for addition.

3.1.2 Identifying levels of soy leghemoglobin in the food supply

The applicant has demonstrated that soy leghemoglobin levels can be quantitatively identified in the Impossible burger patty based on ultrahigh performance liquid chromatography methodology. An appendix document provided as CCI to the application described the applicants procedure for measurement of soy leghemoglobin concentration in the soy leghemoglobin preparation (LegH Prep) and Impossible meat analogue burger patties. FSANZ notes that test results on these products stored under various conditions exhibited high levels of consistency in testing.

FSANZ understands that enforcement agencies have broad statutory powers under Australian and New Zealand food laws to inspect and compel the production of information and records from food businesses. These powers appear broad enough to enable the audit of any production records of any manufacturing facility to validate the amount of soy leghemoglobin in the form of LegH Prep being added to meat analogue products. FSANZ also notes the applicant's advice that it is willing to share its methods of analysis for detecting soy leghemoglobin in the form of LegH Prep in meat analogue products with enforcement agencies on a confidential basis.

3.2 Labelling requirements

FSANZ has assessed how existing labelling requirements will apply to soy leghemoglobin as an ingredient. In response to comments at the 1st CFS we have also considered how the existing labelling requirements will apply to meat analogue products containing soy leghemoglobin as an ingredient.

3.2.1 Name of ingredient

Generic labelling provisions in section 1.2.4—4 of Standard 1.2.4 – *Information requirements – statement of ingredients* require ingredients to be identified in a statement of ingredients on food labels using a name by which they are commonly known, or a name that describes its

true nature, or a generic ingredient name if one is specified in the table to section S10—2. There is no requirement for a statement of ingredients for a food for sale that is not required to bear a label (see section 1.2.1—9 of Standard 1.2.1).

The applicant states the common name of this ingredient is 'soy leghemoglobin'. FSANZ considers the generic requirements for labelling of soy leghemoglobin as an ingredient will enable consumers to make informed choice.

3.2.2 Mandatory declaration of certain foods or substances in food

Section 1.2.3—4 of Standard 1.2.3 – *Information requirements – warning statements, advisory statements and declarations* requires the declaration of soybean when soybean or soybean products are present in a food for sale as an ingredient or an ingredient of a compound ingredient, and when present as a food additive or processing aid (or ingredients or components thereof). The addition of soy leghemoglobin as an ingredient in a meat analogue product would trigger a declaration for the presence of soybean on the label (see paragraph 1.2.1—8(1)(d) of Standard 1.2.1). If the food is not required to bear a label, allergen information must be displayed in connection with the display of the food or provided to the purchaser on request (see paragraph 1.2.1—9(7)(b) of Standard 1.2.1).

Food sold to a caterer in a package must include the soybean declaration on the label, as required by paragraph 1.2.1—15(c) of Standard 1.2.1 – *Requirements to have labels or otherwise provide information*.

Provision of this information will enable food-allergic consumers and their caregivers to make informed, safe food choices.

3.2.3 Labelling as ‘genetically modified’

As discussed in the risk and technical assessment report (SD1), novel DNA and novel protein from genetically modified *P. pastoris* strain will be present in the meat analogue product from a liquid preparation (LegH Prep) which contains the soy leghemoglobin. As noted in Section 1.2 of this report, the applicant plans to sell their meat analogue products containing soy leghemoglobin directly to consumers as packaged products (as well as to suppliers).

Section 1.5.2—4 of Standard 1.5.2 – *Food produced using gene technology* sets out the requirement to label certain food as ‘genetically modified’. Subsection 1.5.2—4(3) states that if the genetically modified food is an ingredient in a packaged food for sale (among other things e.g. a substance used as a food additive), the information may be included in the statement of ingredients.

If the food for sale is intended for immediate consumption and is prepared and sold from for food premises and vending vehicles (including restaurants, takeaway outlets, caterers and self-catering institutions), it is exempt from the requirement to label food as ‘genetically modified’ (paragraph 1.5.2—4(1)(e)).

However, the Code requires information relating to foods produced using gene technology to be on labelling for food sold to a caterer[12] (paragraph 1.2.1—15(f) of Standard 1.2.1). Consequently, in relation to such food, a consumer may seek information about the food from the food business.

[12] **Caterer** is defined as a person, establishment or institution (for example, a catering establishment, a restaurant, a canteen, a school, or a hospital) which handles or offers food for immediate consumption (subsection 1.1.2—2(3) of Standard 1.1.2 – Definitions used throughout the Code.

3.2.4 Nutrition information

Standard 1.2.8 – *Nutrition information requirements* sets out requirements for a nutrition information panel (NIP) to be provided on a package of food in certain circumstances. Information that must be contained in an NIP include (among other things) the average energy content and average quantity of protein, carbohydrate, sugars, fat and sodium in a serving of the food and a unit quantity of the food. The addition of soy leghemoglobin would contribute to the iron content of meat analogue products. There is no requirement for iron to be declared in the NIP of a packaged meat analogue product unless a nutrition content claim or health claim is made (see subparagraph 1.2.8—6(1)(d)(iv)).

3.2.5 Nutrition content and health claims

Existing requirements and conditions for making voluntary nutrition content and health claims are set out in Standard 1.2.7 – *Nutrition, health and related claims* and Schedule 4 of the Code. These requirements and conditions would apply to meat analogue products containing soy leghemoglobin as an ingredient.

As noted in Section 3.2.4 above, the addition of soy leghemoglobin would contribute to the total iron content of meat analogue products. Based on the amount of iron indicated by the applicant as contributed from soy leghemoglobin, meat analogue products may meet the requirements for making a ‘ source of’ or ‘good source of iron’ nutrition content claim.

Food that meets the general claim conditions for making nutrition content claims about certain properties of food, may also be eligible to make a general level health claim. Section S4—5 lists the conditions for permitted general level health claims for properties of food, including iron. General level health claims are also subject to other conditions in Standard 1.2.7 and include the requirement for a systematic review to substantiate a food-health relationship that is not already mentioned in section S4—5.

High level health claims must be based on a food-health relationship pre-approved by FSANZ. Section S4—4 lists the permitted high level health claims and relevant conditions that must be met by suppliers.

The onus is on the supplier to determine whether their food product meets the conditions and requirements before making a nutrition content claim or a health claim.

3.2.5.1 Restrictions on nutrition content claims in relation to vitamins and minerals added to foods

Section 1.3.2—4 of Standard 1.3.2 – *Vitamins and minerals* applies if a vitamin or mineral has been used as a nutritive substance in a food listed in section S17—4.

This section states a claim must not be made that the percentage (%) RDI of the vitamin or mineral (including the amount added and the amount naturally present) in a reference quantity of food is greater than the percentage that is specified as the maximum % RDI claim for that vitamin or mineral in the table to section S17—4. Section S17—4 sets out the permitted uses of particular vitamins and minerals for various types of food, including ‘analogues of meat’.

Depending on the serving size of the meat analogue product, the amount of iron present and whether claim conditions have been met, a % RDI declaration must be made in the NIP when a ‘source of’ or ‘good source of iron’ nutrition content claim is made elsewhere on the label.

3.2.6 Representations

3.2.6.1 Marketing of meat analogue products

The Code requires that, unless prescribed, the name of the food must be sufficient to indicate the true nature of the food (paragraph 1.2.2—2(1)(b)).

Subsection 1.1.1—13(1) includes requirements for food sold with a specified name or representation. For example, subsection 1.1.1—13(4) states that if a food name is used in connection with the sale of a food, the sale is taken to be the sale of the food as the named food, unless the context makes it clear that the intention is otherwise (e.g. if the name 'sausage' is used in connection with the sale of a food, it is taken that the food is a 'sausage' as defined in subsection 1.1.2—3(2) of Standard 1.1.2; however, the context within which a soy sausage is sold is indicated by the word 'soy' in the name of the product, indicating that the product is not a meat product to which Standard 2.2.1 – *Meat and meat products* applies).

Requirements in the Code work in conjunction with requirements in consumer protection legislation in Australia and New Zealand which prohibit misleading or deceptive conduct, and false or misleading representations about goods and services. In Australia, the Australian Competition and Consumer Commission (ACCC) enforces the *Competition and Consumer Act 2010* (Cth); and States and Territories enforce their own consumer protection legislation. In New Zealand, the New Zealand Commerce Commission (NZCC) enforces the *Fair Trading Act 1986* (NZ) which prohibits false and misleading conduct by businesses.

FSANZ discussed the marketing of meat analogues with the ACCC and the NZCC in March and April 2020, respectively. Both agencies said they have received some complaints about how meat analogue products are being represented as meat products. However, the ACCC reports the majority of these complaints were from companies producing traditional meat products or rival companies which asserted that consumers were or could be misled by particular products. Very few of these complaints were said to be from consumers who believed they had been misled. NZCC did not provide specific comment on complaints received.

When assessing a complaint, both the ACCC and NZCC state that they consider whether the overall representation of the product is misleading. For example, a product that is clearly and prominently labelled 'vegan', 'vegetarian' or 'meat free' is unlikely to mislead a consumer about whether the product is meat or plant based. The ACCC advise they follow a Compliance and Enforcement Policy, whilst the NZCC advise they use their enforcement criteria to assess complaints.

FSANZ notes the applicant has indicated they intend to market their products as 'made from plants'.

FSANZ understands that where there is evidence that consumers are being misled by representations made about food products, enforcement agencies have powers under consumer protection legislation to take appropriate enforcement or compliance action.

3.2.6.2 Consumers and plant-based meat analogue products

In response to submitter comments, FSANZ has considered evidence about consumer trends in meat consumption and consumer understanding of meat analogue products (refer to SD2 – Consumers and meat analogue products in Australia and New Zealand).

The evidence suggests that some consumers in Australia and New Zealand are trying to reduce their meat intake by substituting some of the meat products in their diet with meat analogue products. Evidence also suggests that some consumers believe that meat analogue products have inferior taste and texture characteristics compared to traditional

meat products. Ingredients or technologies that improve these characteristics in meat analogue products may increase their palatability to consumers.

There was little evidence to characterise consumer understanding of meat analogue products based on product label representations. In two studies of Australian and New Zealand consumers, the proportion of consumers reporting they mistakenly purchased a 'plant-based meat alternative product' believing it was meat-based or vice versa was low (nine percent for Australian consumers and six percent for New Zealand consumers). An experimental study of US consumers found that nearly a third of participants incorrectly identified a meat analogue burger patty labelled as 'Beyond Meat ® Beyond Burger' as containing beef mince, when it was displayed side by side with two traditional meat burger patties. However, ingredient lists were not provided for any burger patty and the removal of the underlined terms made little difference to consumers' ability to correctly identify the meat analogue product.

3.2.6.3 Nutritional equivalence of meat analogue products to meat

Nutrition content claims made about a meat analogue product would need to comply with requirements in Standard 1.2.7 (see Section 3.2.5 of this report above). For example, section 1.2.7—9 of the Code states that a claim directly or indirectly comparing the vitamin or mineral content of a food with that of another food must not be made unless the claim is already permitted by the Code.

A packaged meat analogue product would also need to comply with nutrition information requirements, including the requirement for a NIP, in Standard 1.2.8 (see Section 3.2.4 above).

FSANZ notes meat analogue products are intended as meat substitutes, and the Code permits voluntary fortification of these substitute foods in the table to section S17—4 (see sections 1.3.2—3 and 1.3.2—4 of Standard 1.3.2).

This is consistent with the *Ministerial Policy Guideline for the fortification of foods with vitamins and minerals* (the Ministerial Policy Guideline)[13], as discussed in section 5.3. below.

The Code does not regulate all nutritional aspects of meat analogue products and manufacturers can currently market meat analogue products in Australia and New Zealand with or without added vitamins and minerals. Even so, it is unlikely a meat analogue could achieve exact nutritional equivalence to meat when all factors in the food matrix are considered.

3.3 Summary of proposed regulatory measures

Based on its assessment, FSANZ's risk management conclusion is to permit and regulate the use of soy leghemoglobin as both: a nutritive substance in meat analogue products; and a food produced using gene technology, as follows:

- Define 'soy leghemoglobin preparation' in section S26—2, as 'a cell lysate preparation that includes the GM soy leghemoglobin and residual GM proteins from the *Pichia* yeast'.
- Permit the use of the soy leghemoglobin preparation as a food produced using gene technology by listing the preparation with the same gene-gene donor source, and

[13] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-for-the-Fortification-of-Foods-with-Vitamins-and-Minerals

specific conditions of use into the table to subsection S26—3(7) ('Food produced using gene technology of microbial origin').
- Amend Standard 1.3.2 to permit iron in the form of soy leghemoglobin to be *used as a nutritive substance* only in meat analogue products to which section S17—4 applies, with a maximum permitted use level of 0.8% in raw product.
- List soy leghemoglobin (in a soy leghemoglobin preparation) as a permitted form of iron in the table to section S17—3.
- Amend Schedule 3 to include specifications for the identity and purity of a soy leghemoglobin preparation.
- Existing labelling requirements will apply to soy leghemoglobin (in the form of a soy leghemoglobin preparation) enabling consumers to make informed choices.

Consequential amendments are also be proposed to Note 1 of Schedule 3 and the table to subsection S17—4 (these are explained in the Explanatory Statement—Attachment B to this report).

FSANZ has prepared a draft variation to the Code at Attachment A, to give effect to the above.

4 Risk communication

4.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ has developed and adopted a communication strategy for this application. Subscribers and interested parties have been notified about this 2nd CFS via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News.

FSANZ acknowledges the time taken by individuals and organisations to consider this application. All comments are valued and contribute to the rigour of our assessment. Comments received will be taken into account when deciding whether to amend the draft variation at the next stage of assessment.

4.1.1 Targeted consultation

After receiving submissions to the 1st CFS, FSANZ undertook targeted consultation with the applicant and with jurisdictions between February-April 2020. FSANZ's preliminary position at 1st CFS and issues raised in submissions were discussed. FSANZ has responded to relevant issues in the 2nd CFS report (this report – see Tables 1 and 2, Summary of Submissions).

4.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

Amending the Code to permit the *voluntary* addition of soy leghemoglobin in meat analogue products as proposed in this report is unlikely to have a significant effect on international trade, particularly as soy leghemoglobin is already permitted in similar products in other countries.

In addition, current patents held by the applicant are likely to restrict the sale of this ingredient beyond Impossible products for the foreseeable future.

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

5 FSANZ Act assessment requirements

When assessing this Application, and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

5.1 Section 29

5.1.1 Consideration of costs and benefits

FSANZ has assessed soy leghemoglobin (in the form of LegH Prep) as a food produced using gene technology and as a nutritive substance.

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement (RIS) for permitting genetically modified foods (OBPR correspondence dated 24 November 2010, reference 12065) and for the voluntary addition of nutritive substances to foods (OBPR correspondence dated 16 April 2013, reference 14943).

However, for the purposes of meeting FSANZ Act considerations, FSANZ has given consideration to the costs and benefits that may arise from the measure sought by the application. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from a proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from that proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo, i.e. rejecting the application. This analysis considers permitting the voluntary use of soy leghemoglobin (in the form of LegH Prep) in meat analogue products as a substance *used as a nutritive substance* (permitted form of iron) and as a *food produced using gene technology*.

FSANZ considers that no other realistic food regulatory measures exist, however information received in response to this 2nd CFS may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting voluntary addition of soy leghemoglobin (in the form of LegH Prep) to meat analogue products.

Industry

Approving this product will provide the applicant with the capacity to earn revenue from their innovation in Australia and New Zealand. Australia and New Zealand businesses will be able to purchase and sell Impossible branded meat analogue products containing soy leghemoglobin (in the form of LegH Prep) if they believe they are likely to receive sufficient revenue in what is a potentially growing market sector.

Consumers

If the use of this product is permitted as proposed, consumers may benefit from greater choice of foods, particularly greater choice of fortified meat alternatives. The applicant is targeting their products at 'flexitarians', who they claim (on page 62 of the application) are looking for "more ethical and environmentally friendly alternative meat products without compromising on attributes such as the taste and texture".

As Impossible products are currently not for sale in Australia and New Zealand, we do not have cost data with which to undertake a market analysis. However, the applicant has provided information on US-specific product retail prices:

- Impossible mince: US$12/lb
- 'Commodity 80/20 ground beef': US$4-6/lb range
- 'Premium, organic ground beef': US$8-9/lb range
- 'Super premium': similar price point to Impossible mince.

This suggests that, in the US, products containing soy leghemoglobin are currently more expensive than their traditional meat counterparts. FSANZ expects this price variation to be similar in Australia and New Zealand if Impossible products are permitted for sale here. For more discussion on consumers and meat analogue products, including consumer motivation to reduce meat intake and the likelihood of meat analogue products misleading consumers, please see Section 2 of the SD2.

Government

There may be incremental but likely inconsequential costs to government in terms of monitoring and enforcement to ensure the final products comply with the Code, and various food and consumer protection laws in Australia and New Zealand.

5.1.2 Conclusions from cost benefit considerations

FSANZ considers that the direct and indirect benefits that may arise from permitting the applicant's soy leghemoglobin in meat analogue products, as proposed, likely outweigh the associated costs.

FSANZ acknowledges the information received in response to the 1st CFS for this application. Additional information received in response to this 2nd CFS may enable FSANZ to undertake a more quantitative-based assessment of the associated wider costs and benefits in permitting soy leghemoglobin in meat analogue products. This will depend on the nature of data or information received in submissions and may result in FSANZ arriving at a different conclusion.

5.1.3 Other measures

FSANZ is not aware of any measures which would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

5.1.4 Any relevant New Zealand standards

There are no relevant New Zealand Standards.

5.1.5 Any other relevant matters

Other relevant matters are considered below.

5.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

5.2.1 Protection of public health and safety

FSANZ has completed a risk and technical assessment (see SD1) which is summarised in Section 2 of this report. The assessment concluded that there are no public health and safety concerns associated with permitting the use of soy leghemoglobin in the form of LegH Prep in meat analogue products as proposed.

5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Existing labelling requirements would apply to soy leghemoglobin when added as an ingredient to meat analogue products, as discussed in Section 3.2 of this report, which would provide information to enable consumers make informed choice.

5.2.3 The prevention of misleading or deceptive conduct

FSANZ considers the existing labelling requirements described in Section 3.2 of this report are appropriate would address this objective.

5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used the best available scientific evidence to complete an independent assessment of the application. The applicant submitted a dossier of scientific studies as part of its application, and provided additional data or information as requested. Other relevant information including scientific literature, was also identified and reviewed as part of the assessment.

- **the promotion of consistency between domestic and international food standards**

Soy leghemoglobin is permitted for use in Impossible meat analogue products in some countries overseas, including in the US, Canada, Singapore, Hong Kong and Macao. An application is currently being considered by EFSA for permission in the European Union. Permitting the use of soy leghemoglobin as proposed, would promote greater consistency between domestic and international food standards for meat analogue products.

- **the desirability of an efficient and internationally competitive food industry**

Permitting the use of soy leghemoglobin as proposed would promote a competitive food industry, as fast developing new technologies in the production of alternative protein sources take off around the world. Products such as soy leghemoglobin could promote competitive research and development innovation in alternative protein technologies within the Australian and New Zealand food industry.

- **the promotion of fair trading in food**

No negative impact is anticipated on fair trading.

- **any written policy guidelines formulated by the Forum on Food Regulation**

FSANZ had regard to the Ministerial Policy Guideline in relation to soy leghemoglobin as a form of iron. *Specific order policy principles – Voluntary fortification* states the "voluntary addition of vitamins and minerals to food should be permitted to enable the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence)". Based on current Code permissions, FSANZ previously considered the fortification of meat analogue products with iron is acceptable as it brings the nutritional profile of these foods closer to meat, the traditional counterpart, and provides a fortified option for consumers looking for alternative choices to meat.

The nutritional impact assessment in Section 2.5 of SD1 indicates that, although there are multiple factors that impact the bioavailability of iron in humans, in general, haem iron is more bioavailable than non-haem iron. The use of a form of iron closer to that found in the traditional counterpart food more closely upholds the principle of nutritional equivalence.

In the Code, there are currently 17 permitted forms of ferric or ferrous iron in section S17—3 with which manufacturers can fortify their products. There are no sources of haem iron permitted, therefore there are currently no sources of haem iron in meat analogue products.

FSANZ concludes that the use of a form of haem iron in meat analogue products is arguably closer to that found in the traditional counterpart than currently permitted forms of iron and therefore the Ministerial Policy Guideline principle on nutritional equivalence has been met.

FSANZ notes that, in November 2019, the Australia and New Zealand Ministerial Forum on Food Regulation asked the Food Regulation Standing Committee to consider regulatory and labelling issues relating to analogue foods, with a view to developing a policy guideline[14]. Currently, there is no other relevant policy guidance.

5.4 Conclusion

FSANZ has assessed application A1186, concluding soy leghemoglobin and the form of LegH Prep raises no public health and safety concerns associated with its use in meat analogue products, at the proposed maximum use level of 0.8% soy leghemoglobin. FSANZ also considered the application against other statutory requirements in Section 18 of the FSANZ Act. The approach has given regard to the best available science, international consistency and industry trade and competition (high level principles in the ministerial policy guideline) as well as to the relevant policy guidelines in accordance with subsection 18(2) of the Act.

As requested by stakeholders during the 1st CFS, FSANZ additionally considered factors related to the applicant's meat analogue products containing soy leghemoglobin and the potential for Australian and New Zealand consumers to be misled by meat analogue products (see above in Section 3.2 and SD2).

FSANZ concluded that the proposed permission promotes greater consistency between domestic and international food standards and supports an efficient and internationally competitive food industry, as soy leghemoglobin is currently permitted in meat analogue products in other countries. The permission for use of soy leghemoglobin to be (i) *used as a nutritive substance*, and soy leghemoglobin in the form of LegH Prep (ii) as *food produced*

[14] See Communique

using gene technology provides an alternative option for the iron fortification of meat analogue products across Australia and New Zealand. Additionally, the proposed permission paves the way for future product innovation in the alternative protein industry.

Having considered the submissions to the 1st CFS, FSANZ now invites stakeholder input on the proposed draft variation to the Code.

6 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

A Mock-up of Schedules 3 and 26 (prepared *as if* the draft variations of both A1155 (another application under review by FSANZ) and A1186 have been approved) is at Attachment C. The draft variation for A1186 was prepared taking into account the draft variation for A1155 as approved by FSANZ on20 December 2019. As the draft variation for A1155 is currently under review and not yet in force, the Code, as is, does not include the relevant amendments. Attachment C was added to assist stakeholders in understanding the draft variation for A1186.

7 References

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Attachments

A. Draft variation to the *Australia New Zealand Food Standards Code*
B. Draft Explanatory Statement
C. Mock-up of proposed drafting for Schedule 3 and Schedule 26
D. Full list of submitters at 1st CFS

Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*

Food Standards (Application A1186 – Soy Leghemoglobin in meat analogue products) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Name of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1186 – Soy Leghemoglobin in meat analogue products) Variation*.

2 Variation to standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Standard 1.3.2 is varied by inserting after section 1.3.2—7

1.3.2—8 Use of soy leghemoglobin as a nutritive substance

(1) Iron in the form of soy leghemoglobin must not be used as a nutritive substance in a food other than a meat analogue product to which section S17—4 applies.

(2) For the purposes of subsection (1), soy leghemoglobin must not be present in a meat analogue product in its raw state at a concentration greater than 0.8%.

[2] Schedule 3 is varied by

[2.1] omitting from Note 1 the words 'Section 1.1.1—15 requires', substituting 'Sections 1.1.1—15 and S26—3 require'

[2.2] inserting in the table to subsection S3—2(2) in alphabetical order

soy leghemoglobin preparation	section S3—42

[2.3] inserting after section S3—41

S3—42 Specification for a soy leghemoglobin preparation

Note Subsections S26—3(5) and (7) require a soy leghemoglobin preparation to comply with the specifications set out in this section.

For a soy leghemoglobin preparation, the specifications are the following:

(a) soy leghemoglobin protein—maximum 9.0%;
(b) soy leghemoglobin protein purity—minimum 65%;
(c) appearance—dark red concentrated liquid;
(d) solids— maximum 26%;
(e) fat—maximum 2.0%;
(f) carbohydrate—maximum 6.0%;
(g) pH—5-10;
(h) moisture—maximum 90%;
(i) ash—maximum 4.0%;
(j) lead—maximum 0.4 mg/kg;
(k) arsenic—maximum 0.05 mg/kg;
(l) mercury—maximum 0.05 mg/kg;
(m) cadmium—maximum 0.2 mg/kg;
(n) microbiological:
    (i) *Escherichia coli*—negative to test;
    (ii) *Salmonella spp*.—negative to test;
    (iii) Listeria monocytogenes—negative to test.

[3] Schedule 17 is varied by

[3.1] inserting in Column 2 of the table to section S17—3 for the mineral 'Iron', in alphabetical order

	Soy leghemoglobin in a soy leghemoglobin preparation that is listed in Schedule 26 and complies with any corresponding conditions listed in that Schedule.

[3.2] omitting from the table to section S17—4, under the heading 'Analogues derived from legumes'

Analogues of meat, where no less than 12% of the energy value of the food is derived from protein, and the food contains 5 g protein per serve of the food

substituting

Analogues of meat, where no less than 12% of the energy value of the food is derived from protein, and the food contains no less than 5 g protein per serve of the food

[4] **Schedule 26** is varied by

[4.1] inserting in subsection S26—2(2), in alphabetical order

soy leghemoglobin preparation means a cell lysate preparation that:

(a) is derived from *Pichia Pastoris* containing the gene for leghemoglobin c2 from *Glycine max*; and

(b) contains soy leghemoglobin.

[4.2] inserting in the table to subsection S26—3(7), in numerical order

3	**Soy leghemoglobin preparation**	*Pichia Pastoris* containing the gene for leghemoglobin c2 from *Glycine max*	1. May only be added to a meat analogue product to enable the use in that product of soy leghemoglobin as a nutritive substance in accordance with Standard 1.3.2. 2. Must comply with the specifications set out in section S3—42.

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1186 which sought to permit the voluntary use of a soy leghemoglobin, produced by microbial fermentation of a GM yeast (*P. Pastoris*), to meat analogue products. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to the Code.

2. Purpose

The Authority has prepared a draft variation amending the Code to permit iron in the form of soy leghemoglobin, produced in a particular way, to be used as a nutritive substance in meat analogue products to which section S17—4 applies, up to a specified maximum level.

The soy leghemoglobin must be in a soy leghemoglobin preparation that is listed in Schedule 26 and complies with corresponding conditions listed in that Schedule.

The draft variation includes amendments to Standard 1.3.2, and Schedules 3, 17 and 26 to achieve this purpose.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1186 includes a total of two public consultation rounds following an assessment and the preparation of a draft variation and associated assessment summaries.

Submissions were first called for on the Authority's safety and risk assessment, and preliminary regulatory position on 20 December 2020 for a six week consultation period.

A Regulation Impact Statement (RIS) was not required because the Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption, permitting:

- the voluntary use of genetically modified food (OBPR correspondence dated 24 November 2010, reference 12065), and
- the voluntary addition of nutritive substances to foods (OBPR correspondence dated 16 April 2013, reference 14943).

The use of soy leghemoglobin in the form of LegH Prep to meat analogue products, as permitted by the draft variation, is voluntary. In addition, this permission is likely to have only a minor impact on business and individuals because it is a minor, deregulatory change that

allows for the introduction of a food product to the food supply which has been determined to be safe.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1]

Item [1] varies Standard 1.3.2 by inserting after section 1.3.2—7, new section 1.3.2—8, which lists conditions for the permitted use of soy leghemoglobin as a nutritive substance. The conditions are:

- iron in the form of soy leghemoglobin must not be used as a nutritive substance in food other than meat analogue products to which section S17—4 applies; and
- soy leghemoglobin must not be present in a meat analogue product in its raw state at a concentration greater than 0.8%.

Item [2]

Item [2] makes the following amendments to Schedule 3.

Sub-item [2.1] varies Note 1 of Schedule 3 by omitting the words 'Section 1.1.1—15 requires', and substituting 'Sections 1.1.1—15 and S26—3 require'. The effect of this amendment is to explain that section S26—3 requires certain food produced using gene technology, for example—soy leghemoglobin, to comply with any relevant specifications in Schedule 3. This is in addition to the same requirement in section 1.1.1—15 applying to other types of substances.

This amendment is consequential to the amendments made to the table to subsection S26—3(7) in sub-item [4.2] below.

Sub-item [2.2] varies the table to subsection S3—2(2) by inserting the substance 'soy leghemoglobin preparation' in column 1 of the table in alphabetical order, and 'section S3—42' as the corresponding provision in column 2 of the table.

Sub-item [2.3] varies Schedule 3 by inserting a new section S3—42 after section S3—41. The new section sets out specifications for a soy leghemoglobin preparation. A note is also included explaining that subsections S26—3(5) and (7) require a soy leghemoglobin preparation to comply with the specifications set out in section S3—42.

Item [3]

Sub-item [3.1] varies the table to subsection S17—3 by inserting 'Soy leghemoglobin in a soy leghemoglobin preparation that is listed in Schedule 26 and complies with any corresponding conditions listed in that Schedule', alphabetically into Column 2 of the table under the entry for the mineral 'Iron' in column 1 of the table.

The effect of this amendment is that this *particula*r soy leghemoglobin is a permitted form of iron for the purposes of subsection S17—3.

Sub-item [3.2] varies the table to section S17—4 under the heading 'Analogues derived from legumes' by omitting 'Analogues of meat, where no less than 12% of the energy value of the

food is derived from protein, and the food contains 5 g protein per serve of the food' and substituting with, 'Analogues of meat, where no less than 12% of the energy value of the food is derived from protein, and the food contains no less than 5 g protein per serve of the food'.

The effect of the amendment in item [3.2] is that the vitamins and minerals (and their corresponding maximum claim amounts) listed for analogues of meat under the heading 'Analogues derived from legumes' in the table to section S17—4, will now relate to analogues of meat with the following properties:

- no less than 12% of the energy value of the food is derived from protein; and
- the food contains *no less than* 5 g protein per serve of the food.

Item [4]

Sub-item [4.1] varies subsection S26—2(2) by inserting the definition for 'soy leghemoglobin preparation' into that subsection, in alphabetical order. 'Soy leghemoglobin preparation' is defined as a cell lysate preparation with the following components—the preparation:

- derives from *Pichia Pastoris* containing the gene for leghemoglobin c2 from *Glycine max*; and
- contains soy leghemoglobin.

Sub-item [4.2] varies the table to subsection S26—3(7) by inserting as **item 3** in column 1 of that table, the substance 'soy leghemoglobin preparation', in numerical order (by item number indicating the order in which the substance is permitted by the Code).

Note: The table to subsection S26—3(7) does not currently exist in the Code, but is proposed in the drafting of A1155, an application currently under review by FSANZ. The drafting of A1155 also inserts two substances into the new table. At the point of preparing this Explanatory Statement, the soy leghemoglobin preparation is the third substance inserted into the table to subsection S26—3(7).

Sub-item [4.2] also inserts in column 2 of the table to subsection S26—3(7), the source of the permitted soy leghemoglobin preparation as '*Pichia pastoris* containing the gene for leghemoglobin c2 from *Glycine max*'. In other words, only a soy leghemoglobin preparation from that source is permitted under the Code.

Last, sub-item [4.2] inserts the following conditions, corresponding to the soy leghemoglobin preparation, in column 3 of the table to subsection S26—3(7):

- the preparation may only be added to a meat analogue product to enable the use, in that product, of soy leghemoglobin as a nutritive substance in accordance with Standard 1.3.2; and
- the preparation must comply with the specifications set out in section S3—42.

A soy leghemoglobin preparation listed in the table to subsection S26—3(7) must comply with both of those conditions (this requirement is included in the A1155 drafting)

Attachment C – Mock-up of proposed drafting for Schedule 3 and Schedule 26

Schedule 3 Identity and purity

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Standard 1.1.1 relates to introductory matters and standards that apply to all foods. Sections 1.1.1—15 and S26—4 require certain substances to comply with relevant specifications. This Standard sets out the relevant specifications.

Note 2 The provisions of the Code that apply in New Zealand are incorporated in, or adopted under, the *Food Act 2014* (NZ). See also section 1.1.1—3.

S3—1 Name

This Standard is *Australia New Zealand Food Standards Code* – Schedule 3 – Identity and purity.

Note Commencement:
This Standard commences on 1 March 2016, being the date specified as the commencement date in notices in the *Gazette* and the New Zealand Gazette under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

S3—2 Substances with specifications in primary sources

(2) The table to this subsection is:

Relevant provisions

Substance	***Provision***
….	….
Salmonella phage preparation (S16 and FO1a)	section S3—33
Soy leghemoglobin preparation	section S3—42
steviol glycoside mixtures including rebaudioside	section S3—32

….

S3—42 Specification for a soy leghemoglobin preparation

Note Subsections S26—3(5) and (7) require a soy leghemoglobin preparation to comply with the specifications set out in this section.

For a soy leghemoglobin preparation, the specifications are the following:

(a) soy leghemoglobin protein—maximum 9.0%;
(b) soy leghemoglobin protein purity—minimum 65%;
(c) appearance—dark red concentrated liquid;
(d) solids— maximum 26%;
(e) fat—maximum 2.0%;
(f) carbohydrate—maximum 6.0%;
(g) pH—5-10;
(h) moisture—maximum 90%;
(i) ash—maximum 4.0%;
(j) lead—maximum 0.4 mg/kg;
(k) arsenic—maximum 0.05 mg/kg;
(l) mercury—maximum 0.05 mg/kg;
(m) cadmium—maximum 0.2 mg/kg;
(n) microbiological:

(i) *Escherichia coli*—negative to test;

(ii) *Salmonella spp*.—negative to test;

(iii) *Listeria monocytogenes—negative to test.*

Schedule 26 Food produced using gene technology

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code.* See also section 1.1.1—3.

Food produced using gene technology is regulated by paragraphs 1.1.1—10(5)(c) and (6)(g) and Standard 1.5.2. This standard lists food produced using gene technology, and corresponding conditions, for paragraph 1.5.2—3(a).

Note 2 The provisions of the Code that apply in New Zealand are incorporated in, or adopted under, the *Food Act 2014* (NZ). See also section 1.1.1—3.

S26—1 Name

This Standard is *Australia New Zealand Food Standards Code* – Schedule 26 – Food produced using gene technology.

Note Commencement:
This Standard commences on 1 March 2016, being the date specified as the commencement date in notices in the *Gazette* and the New Zealand Gazette under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

S26—2 Interpretation

(1) In this Schedule, headings in bold type are for information only, and do not list food for the purpose of section 1.5.2—3.

(2) In this Schedule:

…

Soy leghemoglobin preparation means a cell lysate preparation that:

(a) is derived from *Pichia Pastoris* containing the gene for leghemoglobin c2 from *Glycine max*; and

(b) contains soy leghemoglobin.

…

S26—3 Permitted food produced using gene technology and conditions

(1) The table to subsection (4) and the table to subsection (7) list permitted food produced using gene technology.

(2) Items 1(g), 2(m), 7(e), (g) and (h), and 9(a) of the table to subsection (4) are subject to the condition that their labelling must comply with section 1.5.2—4.

Note *That section requires the statement 'genetically modified'.*

(2A) Products containing beta-carotene from item 6(b) of the table to subsection (4) are subject to the condition that their labelling must comply with section 1.5.2—4.

(3) Item 2(m) of the table to subsection (4) is also subject to the condition that, for the labelling provisions, unless the protein content has been removed as part of a refining process, the information relating to *foods produced using gene technology includes a statement to the effect that the high lysine corn line LY038 has been genetically modified to contain increased levels of lysine.

(4) The table for this subsection is:

Food produced using gene technology of plant origin

Commodity	***Food derived from:***
…	…

(5) A food listed in the table to subsection (7) must comply with any corresponding conditions listed in that table.

(6) A source listed in the table to subsection (7) may contain additional copies of genes from the same strain.

(7) The table for this subsection is:

Food produced using gene technology of microbial origin

Substance	*Source*	*Conditions of use*
1 2′-O-fucosyllactose	(a) *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori*	1. May only be added to infant formula products and to formulated supplementary food for young children. 2. During the exclusive use period, may only be sold under the brand GlyCare. 3. For the purposes of condition 2 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1155 – 2'-FL and LNnT in infant formula and other products) Variation* and ending 15 months after that date.
2 Lacto-N-neotetraose	(a) *Escherichia coli* K-12 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitides* and the gene for beta-1,4-galactosyltransferase from *Helicobacter pylori*	1. May only be added to the following foods in combination with 2′-O-fucosyllactose that is permitted for use in infant formula products; and formulated supplementary food for young children. 2. During the exclusive use period, may only be sold under the brand GlyCare. 3. For the purposes of condition 2 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1155 – 2'-FL and LNnT in infant formula and other products) Variation* and ending 15 months after that date.
3 Soy leghemoglobin preparation	*Pichia Pastoris* containing the gene for leghemoglobin c2 from *Glycine max*	1. May only be added to a meat analogue product to enable the use in that product of soy leghemoglobin as a nutritive substance in accordance with Standard 1.3.2. 2. Must comply with the specifications set out in section S3—42.

Attachment D – Submitters at 1st CFS

Government (5)

- Department of Health and Human Services, Victoria
- New South Wales Food Authority
- New Zealand Ministry for Primary Industries
- Queensland Health
- South Australia Health

Industry (6)

- Australian Food and Grocery Council
- Beak and Johnston AU/NZ
- Funlab
- Grilled
- New Zealand Food and Grocery Council
- Woolworths AU

Not for profit organisations (4)

- Allergy and Anaphylaxis Australia
- Food Frontier AU
- National Allergy Strategy AU
- The Good Food Institute NZ

Primary production organisations (3)

- Australian Food Sovereignty Alliance
- Beef + Lamb New Zealand Inc.
- Meat and Livestock Association NZ

Consumer organisations (10)

- Carbon Neutral Trust NZ
- Fart Free NZ
- Friends of the Earth AU
- Friends of the Earth NZ
- GE Free NZ
- GE Free Northland NZ
- Grey Power Combined NZ
- Life Sciences Network Inc. NZ
- Physicians and Scientists for Global Responsibility NZ
- Soil and Health Association NZ

Individual submitters (16)

<u>New Zealand</u>

- Boland, M
- Bremer, I
- Carapiet, J
- Davis, V
- Grammer, ZL

- Gaia, B
- Jackson, Sir P & Walsh, Dame F
- Mueller-Glodde, R
- Robinson, M
- Vandeleur, K
- Volker, P

Australia

- Grevillea, J
- Grogan, J
- Hardy, S
- Jones, Col. B
- Macris, J