

15 December 2020
[145-20]

Approval report – Application A1186

Soy leghemoglobin in meat analogue products

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Impossible Foods Inc. for the voluntary addition of soy leghemoglobin, produced by microbial fermentation, in meat analogue products.

On 6 August 2020, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 15 submissions.

FSANZ approved the draft variation on 1 December 2020. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 15 December 2020.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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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 Inc. (the applicant) applied to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the voluntary use of soy leghemoglobin¹ 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/w²) in raw product.

The applicant's soy leghemoglobin intends to provide the nutrition (source of iron), flavour and aroma similar to that of myoglobin, an oxygen storing haem protein found in meat.

The applicant sought permission for soy leghemoglobin as a novel food, nutritive substance and genetically modified (GM) food. No request was made for exclusive permission of the ingredient.

The applicant's soy leghemoglobin is a protein produced from a GM yeast, *Pichia pastoris* (*P. pastoris*). This yeast has been modified to express the leghaemoglobin gene from soybean (*Glycine max*). Soy leghemoglobin would be added to the applicants meat analogue products in the form of a liquid cell lysate preparation (the Preparation)³. The Preparation also contains proteins and genomic DNA from the *Pichia pastoris* 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 assessed both the Preparation and soy leghemoglobin as a food produced using gene technology, due to production methods used.

The addition of soy leghemoglobin can also provide flavouring and colouring. However, FSANZ considers the regulatory approach to not regulate every function of soy leghemoglobin is consistent with that used for some other multi-function substances in the Code (for example, several food additives such as calcium salts also contribute to the calcium content of food, but that does not make them nutritive substances). Additional permissions added to the Code for soy leghemoglobin would not have provided any more mitigation of risk for consumers and enforcement agencies. The applicant accepted FSANZ's proposed variations to the regulatory approach (under Section 30 of the FSANZ Act).

FSANZ did not include an assessment as a novel food because the soy leghemoglobin in the Preparation is produced through GM processes and the Code does not require a GM food to also be permitted as a novel food.

¹FSANZ 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 common 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 g/100 g.

³The applicant's brand name for the liquid preparation containing the soy leghemoglobin ingredient is LegH Prep. For drafting purposes and to future-proof the Code, the term 'soy leghemoglobin preparation' is used in the draft variation.

Two rounds of public consultation have been conducted for A1186. In developing the 2nd CFS, FSANZ held targeted consultation with four Australian jurisdictions and the New Zealand Ministry for Primary Industries/Food Safety, updated the risk and technical assessment report (SD1), and developed a report outlining consumer-related data and information around meat analogue products in Australia and New Zealand (SD2).

FSANZ has undertaken a comprehensive assessment using current internationally agreed practices and processes to assess safety of the Preparation including soy leghemoglobin.

FSANZ has concluded that soy leghemoglobin in the form of the Preparation is safe for human consumption in meat analogue product at levels up to 0.8%.

Stakeholder submissions received did not provide any substantive scientific evidence or new arguments that changed the conclusions of FSANZ's evaluation of the safety of the Preparation.

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 the Preparation 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. The Preparation was not genotoxic *in vitro* and did not cause adverse effects in short-term toxicity studies in rats.
- Haem iron from soy leghemoglobin is expected to have similar bioavailability to haem iron from mammalian haem proteins (e.g. myoglobin present in muscle tissue) based on the available data. Soy leghemoglobin has similar structural and physicochemical properties to animal myoglobins, and soy leghemoglobin is completely digested by pepsin thus making the haem group freely available for absorption. However, in the absence of *in vivo* studies, a quantitative comparison of haem iron bioavailability from soy leghemoglobin and other haem proteins is not possible.
- The absence of meat proteins in the proposed meat analogue products may decrease the bioavailability of haem iron from soy leghemoglobin. However, because iron absorption is regulated tightly by the body (increasing in iron-deficient individuals and decreasing in cases of iron overload), and meat analogue products have higher total iron content due to higher content of non-haem iron relative to comparison meat products, any decrease in haem iron bioavailability should not result in a nutritional disadvantage to consumers in Australia and New Zealand.
- Based on a conservative dietary intake assessment that likely overestimated dietary intakes of the Preparation and iron, Australian and New Zealand consumers will not exceed the upper level of intake (UL) for iron.

Since 2016, the Preparation has had a history of safe use in Impossible meat analogue products in other countries, and is currently sold in the United States (US), Canada, Singapore, Hong Kong and Macau.

The proposed permissions support greater international consistency and trade opportunities, as soy leghemoglobin in the Preparation is currently permitted for use in the applicant's Impossible meat analogue product in overseas markets.

Post-marketing surveillance data provided by international regulatory partners has not identified any confirmed adverse events following consumption of meat analogue products containing the Preparation. This is consistent with data provided by the applicant and the outcomes of FSANZ's safety assessment.

Having considered all submissions, and weighing all aspects of the assessment against the statutory requirements, including relevant ministerial policy guidelines, FSANZ approved the draft variation to the Code.

The permissions concerned provide for use of soy leghemoglobin as an alternative iron source in meat analogue products to consumers wishing to reduce or eliminate their intake of meat, and promotes an innovative and competitive food industry in Australia and New Zealand.

1 Introduction

1.1 The Applicant

Impossible Foods Inc. 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 meat analogue 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, in a liquid preparation called 'LegH Prep' (the Preparation)⁴, as a component in meat analogue products (including the Impossible Burger, meatballs, sausages, and as fillings in buns and dumplings).

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). Products containing soy leghemoglobin are intended for consumption by the general population aged 2 years and older.

Soy leghemoglobin is a protein produced by fermentation of genetically modified (GM) yeast *Pichia pastoris* (*P. pastoris*). This yeast has been modified to express the leghaemoglobin gene from soybean (*Glycine max*) and other host proteins that support the expression of leghaemoglobin. The Preparation contains the soy leghemoglobin protein at up to 9%, as well as some residual *P. pastoris* proteins and genomic DNA, and added stabilisers (sodium ascorbate and sodium chloride).

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 the Preparation (Schedule 3). FSANZ understands the applicant has applied for patents in Australia and New Zealand, for the methods of production and specifications of their meat analogue products, and the Preparation⁵.

The maximum proposed use level for soy leghemoglobin is 0.8% (0.8 g/100 g) in raw product as it is the lower end of the myoglobin content of red meat (0.8–1.8%) (Texas A&M Institute, 2019). Additionally, the applicant's testing has indicated this is the maximum use level at which meat analogue products retain palatability. The application indicates that actual levels of soy leghemoglobin 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 indicated that Australian and New Zealand co-manufacturers may be contracted in the future to produce Impossible meat analogue products using locally sourced ingredients,

⁴ The applicant's brand name for the liquid preparation containing the soy leghemoglobin ingredient is LegH Prep. For drafting purposes, the term 'soy leghemoglobin preparation' is used, herein referred to as the Preparation.

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

however the production of the Preparation will continue in an Impossible Foods 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 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 analogue products providing the meat analogue product meets 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 is proposed to be used as a source of iron, meat analogue products 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 analogue products 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*.

Soy leghemoglobin 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 the Preparation must be given in accordance with Standard 1.5.2 (i.e. the Preparation 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*. The Preparation 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, one 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.

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 caterer⁷ 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

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 Standard 1.1.2 – Definitions used throughout the Code).

to a caterer). The requirement to label food as 'genetically modified' does not apply to GM food intended for immediate 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 discussion about labelling requirements in the Code that would apply to soy leghemoglobin, see section 3.2 of this report.

1.3.2 International Regulations

1.3.2.1 Codex

Codex provides general guidance on safety assessments, 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 the Preparation for toxicological 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/WHO⁸ 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 US FDA GRAS status (GRN 737) in July 2018 to use its 'soy leghemoglobin'⁹ at levels up to 0.8% in its raw ground (minced) beef analogue products as a 'flavour optimiser'. In addition, in response to a request by the US FDA, the applicant lodged a colour additive petition to the US FDA 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 US FDA 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 2019¹⁰. US FDA currently has also a policy statement that identifies fortification practices that manufacturers are encouraged to follow. However, this policy is guidance only, and US FDA 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' from Health Canada for use in ground beef analogues at level up to 0.8% soy leghemoglobin. As of September 2020, Impossible products have been available in stores and catering venues across Canada.

⁸ FAO is the Food and Agriculture Organization of the United Nations; WHO is the World Health Organization.

⁹ Some international regulatory bodies have provided permission for 'soy leghemoglobin', FSANZ understands this is for the soy leghemoglobin in the Preparation.

¹⁰ <https://www.regulations.gov/document?D=FDA-2018-C-4464-0002>

1.3.2.4 Singapore

The Agri-Food and Veterinary Authority (now the Singapore Food Agency) in August 2018 permitted the 'soy leghemoglobin' in their *List of Other Food Additives/Ingredients that are Permitted Under the Singapore Food Regulations* in 'plant-based meat analogues' at levels up to 0.45% (SFA 2019). FSANZ consulted SFA to discuss their assessment processes, and to understand why their permissions were set at 0.45% instead of 0.8% as requested in application A1186. The SFA representatives indicated they undertook a risk analysis similar to FSANZ, and that the level was permitted because that was what Impossible Foods applied for. SFA representatives confirmed that the applicant would have to apply for a higher use level, if desired.

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

In October 2019, European Food Safety Authority (EFSA) received Impossible Foods application to authorise the sale of soy leghemoglobin (in the form of the soy leghemoglobin preparation) from genetically modified *P. pastoris* as a flavouring in meat analogue products¹¹ (requestor member state – The Netherlands). The status of this application is '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 was assessed under a Major Procedure.

FSANZ extended the consideration period for the application by four months under subsection 109(4) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act). We determined that it was not practicable to consider the application within the 12 month period (for a Major procedure) due to its complexity.

¹¹ For further information see [EFSA register of questions](#); mandate number M-2019-0132, Question number EFSA-Q-2019-00651, Application number GMO-2019-0008;.

1.6 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on Gazettal. The approved draft variation is at Attachment A.

The related 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.

2 Summary of the assessment

2.1 Summary of issues raised in submissions

FSANZ received a total of 16 submissions to the 2nd CFS: four (4) government jurisdictions, five (5) industry (including the applicant), two (2) Not for Profit organisations, three (3) consumer groups and two (2) private submitters (see Attachment D for a full list of submitters).

The submissions have been published on the [A1186 webpage](#). Across the different submitter groups, FSANZ notes eight submitters (including the applicant) supported the proposed permission, including the proposed draft variation to the Code, and labelling requirements outlined in the 2nd CFS report.

Issues or questions requiring clarification from relevant submissions have been summarised and responses given in Table 1 (relating to soy leghemoglobin or the Preparation) and Table 2 (relating to the applicant's Impossible Foods meat analogue products, or analogue products more broadly).

2 Summary of the findings

2.1 Summary of issues raised in submissions

Table 1. Submission issues relating to soy leghemoglobin or the Preparation

#	Issue	Raised by	FSANZ response (including any amendments to drafting)
Regulatory approach, drafting and enforcement			
1.	<p>FSANZ should regulate soy leghemoglobin as a food additive (flavouring):</p> <ul style="list-style-type: none"> This is its stated purpose in the application, and meets the definition for food additive under Standard 1.1.2. There is a concern that under paragraph 1.1.2(a)(i) Soy leghemoglobin (which has US FDA GRAS status as a flavouring), could be listed by the US Flavour and Extract Manufacturers' Association (FEMA). This could see soy leghemoglobin added as a flavouring substance, at Good Manufacturing Practice (GMP) levels rather than the proposed 0.8%, to foods in Australia and New Zealand. 	SA Health	<p>The 2nd CFS report outlines FSANZ's rationale for the proposed regulation of soy leghemoglobin (see section 3.1). For the reasons stated in section 3.1, FSANZ is not aware of any evidence that warrants a change to regulatory approach (i.e. to categorise soy leghemoglobin as a food additive (flavouring), instead of, or as well as, a nutritive substance as requested in the application).</p> <p>FSANZ notes no other jurisdiction raised this as a concern at the 2nd CFS.</p> <p>FSANZ recognises many substances added to food may also impart flavour and/or colour without being regulated as such. FSANZ also notes there is currently no listing for 'soy leghemoglobin' under the FEMA flavouring list. The applicant highlighted that US regulations do not require a FEMA GRAS notification for new flavours, including for soy leghemoglobin. Instead, the applicant submitted a GRAS Notice directly to the US FDA and received a "No Questions" letter. The applicant has indicated they will not apply to FEMA.</p>
2.	<p>Submitter considers it premature for FSANZ continue the assessment of soy leghemoglobin while EFSA is currently conducting an assessment on the same product.</p>	The Victorian Departments and PrimeSafe (VD/PS)	<p>The FSANZ Act sets out statutory timelines for assessment procedures. These do not include placing an assessment on hold for the outcome of an overseas agency's assessment of the same product.</p>

#	Issue	Raised by	FSANZ response (including any amendments to drafting)
			FSANZ highlights that independent evaluations have been completed by the US FDA, Canada and Singapore authorities. Each of these assessments have concluded that soy leghemoglobin is safe under proposed use conditions.
3.	The drafting unit of 0.8% level for soy leghemoglobin in raw meat analogue product is not consistent with mg/kg units used elsewhere in the Code for maximum permitted levels.	SA Health	FSANZ acknowledges that mg/kg is used as a common measurement in the Code, however the percentage (%) measurement is also consistently used throughout the Code. For example, within Schedule 17 for vitamins and minerals, Schedule 4 for health claims, and Standard 1.2.4 for compound ingredient labelling.
4.	Low use levels (e.g. 0.05%) of soy leghemoglobin may not contribute nutritionally to the diet, and is therefore not used as a nutritive substance. A manufacturer may use the minimum use level to reduce the cost of the product. This could mislead consumers regarding iron consumption.	SA Health	<p>Permission for voluntary addition of a vitamin or mineral is not dependent on its contribution to the total diet; there are no minimum composition levels set for such vitamins and minerals in the Code since voluntary rules also allow for no addition.</p> <p>Likely use levels of soy leghemoglobin (0.25% and 0.45% for pork and beef products, respectively) are determined based on nutrition, flavour and aroma profiles of myoglobin in animal products. FSANZ notes there is also a colouring effect. Adding less would not achieve these same profiles in the final meat analogue products. The applicant has patents to protect the ingredient from misuse and, as stated in the 2nd CFS, has agreed to share their method for detecting soy leghemoglobin in products with enforcement agencies who wish to monitor Impossible meat analogue products in Australia and New Zealand.</p> <p>Consumer protection and food laws in Australia and New Zealand prohibit misleading or deceptive conduct, and false or misleading representations related to food. Existing minimum requirements for declaration of iron (i.e. $\geq 10\%$ RDI/100 g) are established in the Code so that consumers can make informed decisions about the food they consume, and are not misled (see section 3.2 of this report).</p>

#	Issue	Raised by	FSANZ response (including any amendments to drafting)
5.	<p>The 'soy leghemoglobin preparation' specification under Schedule 3 mostly contains quality parameters specific to the applicant's production method. This is restrictive to innovation and trade. These quality parameters (appearance, solids, ash, moisture etc.) do not serve to protect public health and safety and are not required to define soy leghemoglobin as a nutritive substance.</p>	SA Health	<p>Specifications in Schedule 3 are for identity and purity, and include (among other things) quality parameters that relate to identity such as 'appearance', 'description', and relevant compositional factors such as 'moisture' and 'ash' for purity.</p> <p>FSANZ acknowledges that the new specification is unique to the applicant's Preparation, and therefore the quality parameters are specific to the applicant's manufacturing process. However, another soy leghemoglobin product could be produced in the future using a different gene-gene donor and manufacturing process. This would require pre-market consideration and likely an application. At that time FSANZ would consider any relevant specification for a 'soy leghemoglobin preparation' and decide if it needed to change to allow for innovation and trade efficiencies.</p> <p>Furthermore, the applicant has confirmed that they will not be supplying the Preparation ingredient to any distributor or any third party for use in any meat analogue products other than Impossible branded ones. This does not restrict innovation or trade in meat analogues.</p>

#	Issue	Raised by	FSANZ response (including any amendments to drafting)
6.	<p>The microbiological detection limits outlined in the proposed specifications, if required to protect public health and safety, should be included in the microbiological standard in the Code, which would reduce 'vertical standards' created in the Code which are cumbersome to navigate.</p>	SA Health	<p>Standard 1.6.1 <i>Microbiological limits in food</i> and Schedule 27 <i>Microbiological limits for food</i> are the standards in the Code which set out microbiological limits for food at the point of sale; and relate to nominated foods, or classes of foods. These standards do not apply to substances used in food for sale, such as nutritive substances, processing aids and food additives</p> <p>As stated above, when substances (such as the Preparation) are added to food or sold for use in food, they must comply with specifications in Schedule 3. Specifications in Schedule 3 may contain microbiological detection limits for the substances concerned.</p> <p>As the Preparation does not have a specification in the primary or secondary sources listed in relevant sections S3-2 or S3-3, FSANZ is required to list a specification in that schedule. This is common practice and FSANZ is not aware of any difficulty users have in navigating the Code. Although out of scope for this application, jurisdictions are welcome to raise the issue of 'vertical standards' independently.</p>

#	Issue	Raised by	FSANZ response (including any amendments to drafting)
7.	FSANZ has not undertaken a microbiological assessment examining the parameters listed in the specification of soy leghemoglobin for <i>E. coli</i> , <i>Salmonella</i> spp. or <i>Listeria</i> that scientifically justifies their inclusion in a standard.	SA Health	<p>FSANZ has assessed and is satisfied with the microbiological specifications and microbiological safety as provided by the applicant, noting that this specification refers to the Preparation only, not the meat analogue product in which it would be included.</p> <p>The Preparation is required to be manufactured in accordance with current GMP, employing suitable in-process controls to ensure the purity of the final product to a level that is technically feasible. FSANZ has considered the applicant's in-process controls requested as part of the 2nd CFS. These parameters are necessary to meet the Code's requirement that it is the manufacturer's responsibility to provide safe and suitable food.</p> <p>FSANZ has sighted confidential test results and are satisfied that the Preparation complies with the microbiological parameters put in place by the applicant. The inclusion of microbiological parameters in the Preparation's specification in Schedule 3 may assist jurisdictions who wish to audit the Preparation should it ever be sold to Australian and/or New Zealand co-manufacturers producing Impossible meat analogue products.</p>
8.	'Analogues derived from legumes' and 'Meat analogue products' are not defined in the proposed drafting. The difference between the two terms is not clear for enforcement purposes.	SA Health	<p>'Analogues derived from legumes' and 'Meat analogue products' are terms already used in the Code. For example:</p> <p>Section 17—4 <i>Permitted uses of vitamins and minerals</i> includes a food category 'Analogues derived from legumes' with several more specific subcategories one of which is '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'.</p> <p>The term 'analogue' is not defined in the Code. In the absence of a definition in the Code, the ordinary meaning of 'analogue' applies, for example, the Macquarie Dictionary, defines it as: <i>noun</i> 1. <i>something having analogy to something else</i>. In this case, meat. FSANZ is not aware of any other stakeholder concerns with reference to the term 'analogue' in Schedule 17 not being clear.</p>

#	Issue	Raised by	FSANZ response (including any amendments to drafting)
9.	It is unclear from the proposed drafting whether permission is being provided for “soy leghemoglobin” or “soy leghemoglobin preparation”. Using the two terms makes interpretation of the regulation confusing.	SA Health	<p>In the draft variation, permission will be granted for both ‘soy leghemoglobin’ and the GM ‘soy leghemoglobin preparation’ (the Preparation) for different reasons.</p> <ul style="list-style-type: none"> • The Preparation will be permitted as a GM food because it contains the soy leghemoglobin ingredient, GM residual <i>P. pastoris</i> proteins and DNA, and stabilizers. • Soy leghemoglobin contains the haem iron so will be a permitted form of the nutritive substance ‘iron’. <p>The draft variation also controls the amount of soy leghemoglobin added to raw meat analogue product (0.8% w/w), under the nutritive substance permission in Standard 1.3.2.</p> <p>Soy leghemoglobin can only be added to food in the form of the Preparation, which must meet the proposed specification outlined in Schedule 3.</p> <p>FSANZ has clarified the issue under section 3.1 of this report.</p>
10	FSANZ has signalled it will approve soy leghemoglobin for general use in non-Impossible products, based on the drafting’s proposed permission in the more general ‘meat analogue products’.	FOE/GE	<p>FSANZ understands the applicant has applied for patents in Australia and New Zealand for the methods of production, specifications for their meat analogue products, and the Preparation (containing soy leghemoglobin). FSANZ also understands that the applicant may establish co-manufacturing agreements with Australian and New Zealand companies to manufacture Impossible meat analogue products using locally sourced ingredients, with the exception of the Preparation which would be produced in an Impossible manufacturing plant outside of Australia/New Zealand and imported for use in Impossible branded meat analogue products only.</p> <p>Meat analogue products in general will not be authorised to contain the ingredient. Any future soy leghemoglobin product (using a separate method of production and gene-gene donor) would need to undergo pre-market approval before sale in Australia and New Zealand.</p>

#	Issue	Raised by	FSANZ response (including any amendments to drafting)
11	<p>It is assumed that the meat analogue products will be sold cooked. If a meat analogue product is cooked, then proposed use level of 0.8% cannot be enforced as the product is not in the raw state.</p>	SA Health	<p>The applicant intends to import and sell raw Impossible meat analogue product to retail stores and vending vehicles in Australia New Zealand. These can be cooked (by restaurants, takeaway outlets, caterers and self-catering institutions) and then sold to consumers for immediate consumption. Enforcement agencies will therefore have opportunity to test the raw product before it is cooked.</p> <p>Should enforcement agencies wish to analyse soy leghemoglobin in cooked product, FSANZ has provided a calculation for use as a guide in this report – see section 3.1.2.</p> <p>FSANZ also notes enforcers could audit soy leghemoglobin by lot numbers from purchase orders from the applicant.</p>
Labelling			
12	<p>Submissions raised concerns that consumers will be misled by the nature of soy leghemoglobin:</p> <ul style="list-style-type: none"> • There is no requirement to label food as 'genetically modified' in point of sale outlets, fast food chains, on packaging and in advertising. • The applicant's website does not declare that its ingredients are made and sourced from GM ingredients, so consumers will not be made aware that they are eating a GM product and cannot make informed choices. 	GE Free New Zealand (GEF NZ); Grey Power Otamatea Inc. (GPO)	<p>Meat analogue products containing soy leghemoglobin will be required to be labelled as 'genetically modified' as outlined and discussed in sections 1.3.1.3 and 3.2.3 of this report. 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 which states that consumers may seek information about the food from the food business. Further information about GM food labelling can be found on the FSANZ website.</p> <p>FSANZ notes the applicant indicates on their website that they produce soy leghemoglobin through GM processes; they also confirmed they provide education material to their retail customers, which includes information on soy leghemoglobin production processes using GM technology (and other</p>

#	Issue	Raised by	FSANZ response (including any amendments to drafting)
			<p>technological and nutrition considerations – See section 4.3 of this report). FSANZ proposes to liaise with interested jurisdictions to update existing consumer information on our website to include nutritional, science and technological aspects of meat analogue products generally (including GM production processes and varying nutrient levels, such as iron, B12 and protein in meat analogue products). (see section 4.2 of this report)..</p>
13	<p>The 2nd CFS has added a health claim relating to its iron levels, meaning that it is now a high level nutritional claim under subdivision G as well as a product from gene technology.</p> <p>This now requires further scientific evaluation under the high-level claims committee; however we have found it difficult to access their report.</p>	GEF NZ	<p>The draft variation does not contain amendments permitting nutrition content or health claims to be made specifically about meat analogue products containing soy leghemoglobin.</p> <p>Such claims may only be made in accordance with existing requirements in the Code (see, in particular, Standard 1.2.7 and Schedule 4).</p> <p>As noted in the report under section 3.2.5 <i>Nutrition content and health claims</i>, meat analogue products containing soy leghemoglobin will be subject to existing requirements in section S4—3 for a ‘source of’ or a ‘good source of iron’ nutrition content claim.</p> <p>Section S4—5 includes certain permitted food-health relationships about iron for general level health claims, which suppliers may make if the food meets the claim conditions and requirements. However there are none currently permitted for high level health claims about a serious disease in section S4—4.</p> <p>The applicant has not sought to add a food-health relationship about iron for either a general level health or a high level health claim to Schedule 4, and evidence has not been provided to support this. FSANZ has not assessed the application for the purpose of permitting a new food-health relationship about iron for a health claim in the Code.</p>
Safety and technical assessment			

#	Issue	Raised by	FSANZ response (including any amendments to drafting)
14.	In order to provide quality information to those with soy allergies, and their carers, submitter requests that the issue of allergenicity be referred to the Food Allergy and Intolerance Scientific Advisory Group (FAISAG) of experts in allergic disease to confirm FSANZ's conclusions, specific to medical science on allergenicity of soy leghemoglobin	A&AA	<p>The Preparation and Impossible meat analogue products contain ingredients derived from soy. When soy is present in a food it must be declared, or in the case of food not required to bear a label, displayed in connection with the display of the food or provided to the purchaser on request (see section 3.2.2 of this report).</p> <p>However, FSANZ does not consider there is a need for further consideration of allergenicity by FAISAG for the following reasons:</p> <ul style="list-style-type: none"> • FSANZ has compared the novel protein sequences in soy leghemoglobin against those of known allergens, and found no similarities. • Adverse events data reported in the 2nd CFS on over 100 million Impossible burgers sold have not presented any medically-confirmed allergic reactions.
15.	FSANZ did not rely on independent data sources for the risk assessment.	VD/PS; FOE/GE; MC (private)	<p>An application must meet specific data requirements for FSANZ to undertake the safety assessment. These requirements are listed in the FSANZ Application Handbook (Guideline 3.5.1) and follow internationally agreed guidelines established by Codex.</p> <p>Studies (including raw data) supplied by the applicant were independently assessed by FSANZ to ensure they were of sufficient quality, have been conducted in an appropriate manner, and did not raise concerns regarding the safety of the product.</p> <p>In addition to data submitted by the applicant, FSANZ considered information from a variety of other sources including the scientific literature, general technical information, and information from other regulatory agencies, as well as from international bodies such as the OECD and Codex.</p>

#	Issue	Raised by	FSANZ response (including any amendments to drafting)
16.	FSANZ has not outlined all the differences between the two strains: the purity of the soy leghemoglobin protein is only 76% with MYX0541 as opposed to 80% with MXY0291. The fat, ash and carbohydrate levels for the Preparation are also altered.	GEF NZ	It is expected that natural variation will exist between each fermentation run leading to slightly different yields and proportions of constituents. These variations do not pose a public health and safety concern. All production batches of soy leghemoglobin must meet product specifications as proposed in the draft variation for Schedule 3.
17.	Human feeding trials should be undertaken to prove safety of soy leghemoglobin: <ul style="list-style-type: none"> should cover a range of ages and health states, especially due to the variations in pH found in stomach acid due to age and health status should occur for a period of at least 20 years. 	BA/GP; GEFNZ; FOE/GE	Human feeding trials are not routine requirements of GM food safety assessments and are not required anywhere in the world. While FSANZ does not require human feeding studies, FSANZ included current overseas experience as part of the scientific weight-of-evidence considered for this application. The applicant advised they had sold approximately 100 million Impossible burger servings as of March 2020, with no reports of medically-confirmed adverse health effects. This supports the conclusion that the food product poses minimal risk to consumers.
18.	Safety of the <i>P. pastoris</i> host and production strains has not been demonstrated: <ul style="list-style-type: none"> Why is the emphasis on the safety of the <i>P. pastoris</i> host and not the purified soy leghemoglobin product? Should identify the trace <i>P. pastoris</i> proteins present in the preparation and confirm they do not cause anaphylaxis. 	GEF NZ; FOE/GE; GPO; MC (private)	The Preparation comprises cells of the <i>Pichia</i> production strain that have been ruptured (see also the Report: Executive Summary, section 1 <i>Introduction</i> , section 3.3 <i>Summary of proposed regulatory measures</i>). It contains both the novel soy leghemoglobin protein as well as the native <i>Pichia</i> proteins. The safety assessment therefore considered both. In regards to the safety of the <i>Pichia</i> host, the assessment of the organism did not raise any concerns. In addition, as stated above, FSANZ included current overseas experience in their considerations. This supports the conclusion that the Preparation poses minimal risk to consumers.
19.	How can safety data from the two different strains be comparable? <ul style="list-style-type: none"> In regards to allergenicity and toxicity concerns, FSANZ has relied too much on data obtained from the first commercial strain used to produce 	VD/PS; FOE/GE	<u>Allergenicity and toxicity</u> A weight of evidence approach is used for the assessment of potential allergenicity and toxicity of proteins. This internationally

#	Issue	Raised by	FSANZ response (including any amendments to drafting)
	<p>soy leghemoglobin (MXY0291) and should demand the same information from the more recent strain (MXY0541).</p> <ul style="list-style-type: none"> • Did FSANZ consider the genetic differences between the two strains and the potential risks from the gene truncations and base pair differences? • FSANZ argues that available studies with soy leghemoglobin found that it was not genotoxic. Importantly, these studies used strain MXY0291 not MXY0541. 		<p>accepted approach relies on evidence from a number of studies to draw conclusions about the safety of the protein or proteins.</p> <p>One component of the approach relies on the use of bioinformatics to compare the novel protein sequence to that of known toxins and allergens.</p> <p>A second component of the approach examines the susceptibility of the novel proteins to thermal and acid degradation, mimicking the conditions of cooking and digestion.</p> <p>Only if there is biologically relevant similarity to known toxins or allergens and the novel protein is resistant to degradation will further studies be required.</p> <p>In this application, the novel soy leghemoglobin is the same across both production strains. This protein shares no similarity to known toxins or allergens. Soy leghemoglobin was also shown to be susceptible to degradation at normal cooking temperatures and gastric pH. The conclusion from this standard assessment approach was that the soy leghemoglobin poses minimal risk to consumers and did not warrant further studies.</p> <p><u>Genetic differences</u></p> <p>As described in section 2.7.3 in SD1, some base pair changes were identified in an insert lacking a functional terminator. FSANZ concluded “ ... it is unlikely these proteins would be translated because of the non-functional polyadenylation sequence”. This was confirmed by the mass spectroscopy analyses summarised in section 2.3.1 of SD1, where only a single full length soy leghemoglobin protein with the expected sequence was identified. Considering this evidence, FSANZ concluded these differences would not impact safety of the final food product.</p> <p><u>Studies with the Preparation produced by MXY0291</u></p> <p>As noted in FSANZ’s safety assessment, the genotoxicity and toxicity studies using the Preparation produced using the MXY0291 strain are considered to be relevant to the assessment</p>

#	Issue	Raised by	FSANZ response (including any amendments to drafting)
			<p>of the Preparation produced by MXY0541. This is because the expressed soy leghemoglobin protein is equivalent in both strains, several of the <i>Pichia</i> proteins expressed in the Preparation from MXY0541 are also present in the Preparation from MXY0291, and the composition of the Preparation from each strain meets the same specifications. A sufficient body of knowledge exists on the safety of the production organism (<i>P. pastoris</i>) and the proteins in the Preparation from both strains were shown to be digested like other dietary proteins.</p>
20.	<p>A peer-reviewed research article concluded that the plant-based meat analogue food matrix provides conditions more favourable for pathogenic bacterial growth than meat-based counterparts (Luchansky et al 2020). Microbiological risk assessment data for the Impossible Foods meat analogue products is missing from FSANZ's risk assessment document.</p>	VD/PS	<p>The paper by Luchansky et al. presents data on the impact of storage and cooking conditions on the growth of bacteria inoculated onto plant based meat analogue versus beef patties. As the focus is on the patty rather than the soy leghemoglobin, this article is out of scope for this application.</p> <p>However, as outlined in Table 1 of SD1, the microbial limits listed in the specifications include the bacteria (<i>Salmonella</i> spp., Enterohemorrhagic <i>Escherichia coli</i>, including <i>E. coli</i> O157:H7 and <i>Listeria monocytogenes</i>) addressed in the research article. The specification for each bacteria is <i>not detected</i>. This enforceable limit ensures the soy leghemoglobin product poses minimal microbiological risk to consumers.</p>
21.	<p>Submitter considers the duration of the toxicity study (28 days) is too short. It is suggested that the size of the test groups is too small and it is noted that a number of statistically significant changes were observed between controls and the test groups.</p>	FOE/GE	<p>These points were raised previously and addressed in the 2nd CFS. No new information has been provided that would change the conclusions of the safety assessment.</p> <p><u>Sample sizes</u></p> <p>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 group. These numbers are all higher than those recommended in the OECD Test Guideline for 28-day toxicity studies (5/sex/group) and therefore are considered to be adequate.</p>

#	Issue	Raised by	FSANZ response (including any amendments to drafting)
			<p><u>Statistically significant changes</u></p> <p>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 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 (Hayes Principles and Methods of Toxicology, 6th Edition).</p> <p>In the case of the statistically significant differences observed in the 28-day study with the Preparation, 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.</p> <p><u>Study duration</u></p> <p>Proteins known to be toxic to mammals generally cause acute toxicity, so further testing of the Preparation in a 90-day study would not be justified given it is rapidly digested and showed no toxicity in the 28-day study.</p>

#	Issue	Raised by	FSANZ response (including any amendments to drafting)
22	The 14 day toxicity study found that numbers of white blood cells, neutrophils and lymphocytes in males were >25% lower than those of controls. The 28 day study reported statistically significant changes in haematology, liver and clinical chemistry values as well as oestrus cycles. These changes have been ignored as not treatment related and were not fully addressed by the assessment.	GEF NZ	<p>These majority of these points were raised previously and addressed in the 2nd CFS. No new information has been provided that would change the conclusions of FSANZ's safety assessment.</p> <p>As discussed in FSANZ's safety assessment, a dose-response was not observed for the changes in white blood cells in the 14 day study and these changes were not considered to be treatment-related. In addition, these findings were not replicated in the 28 day toxicity study.</p> <p>As noted above, statistically significant differences observed in the 28-day study with the Preparation were not considered to be treatment-related.</p> <p>With respect to differences in oestrus cycling, no dose-response was observed and the differences were considered to be a result of normal variation in oestrus cycling between animals. The additional investigative study confirmed this conclusion.</p>
Iron in soy leghemoglobin			
23	Submitter highlights the evidence the applicant provided to demonstrate the bioavailability of iron from haem was based on extracts of soy leghemoglobin, rather than the Preparation itself	FOE/GE	This evidence was from an in vitro study which provided supporting evidence that the bioavailabilities of iron from soy leghemoglobin and bovine haemoglobin are likely to be similar. Approximately 15-25% of dietary haem iron is absorbed, and there is no evidence to indicate that the bioavailability of haem iron from soy leghemoglobin would lie outside this range.
24	It remains unknown whether the haem iron from soy leghemoglobin may pose that same risk as that from meat. FSANZ dismissed research that suggests that [haem] iron may contribute to an increased risk of colon cancer and other health problems on the basis of two reviews funded by the beef industry.	FOE/GE	The submitter has not provided any new information that would change the conclusions of FSANZ's safety assessment. FSANZ's comments on colon cancer were based on the weight of scientific opinion, including an extensive review by the World Health Organization's International Agency for Research on Cancer (IARC, 2018).

Table 2. Submission issues relating to the applicant's meat analogue products or analogue products more broadly

	Issue	Raised by	FSANZ response (including any amendments to drafting)
	Concerns with misleading consumers		
1.	Could soy leghemoglobin be found in mixed meat products such as a mixture of sausage meat and meat analogue containing leghemoglobin by 'carry over'?	SA Health	FSANZ has consulted with the applicant to enquire about the possibility of a 'hybrid' Impossible meat analogue products, containing a mixture of meat analogue product and meat. Based on the intent of the applicant, combined with their patents, FSANZ does not consider the two products will be mixed. FSANZ discusses further in section 3.1.2 of this report.
2.	The Impossible burger is an ultra-processed food, high in sodium and contains added preservatives. A recent review (Elizabeth et al 2020) found that ultra-processed foods in the diet are associated with higher risks of obesity, heart disease and stroke, type-2 diabetes, cancer, frailty, depression and death.	FOE/GE	<p>FSANZ has assessed the Preparation and soy leghemoglobin for safety and nutritional considerations around soy leghemoglobin. Meat analogue products, such as the Impossible burger are permitted to contain added vitamins and minerals in S17—4 that align with the levels found in meat – the counterpart traditional food. FSANZ notes there are meat analogue products currently for sale in Australia and New Zealand without fortification.</p> <p>FSANZ also clarified the protein criteria in S17—4 for vitamin and mineral addition is a minimum level (see attachment A in this report).</p> <p>Concerns about the entire nutritional profile of meat analogue products, and diets including meat analogue products more broadly are out of scope and, therefore, not addressed under A1186. These concerns may be relevant to future ministerial policy guidance (see point 5 under section 5.3 of this report).</p>
	Labelling		

	Issue	Raised by	FSANZ response (including any amendments to drafting)
3.	<p>The Impossible burger is made from a range of GM ingredients all escaping labelling requirements due to various exemptions. There is also a gap in legislation in that it is not clear whether a food that contains 100% GM ingredients but each ingredient is below the level of labelling is considered 'adventitious' or required to be labelled.</p>	GEFNZ	<p>Exemptions from GM labelling may apply to soy leghemoglobin as an ingredient, as is the status quo for all approved GM foods. A change to existing labelling requirements for GM foods generally would be a policy matter and is outside the scope of this application.</p> <p>Only approved GM foods can either be added as ingredients or present unintentionally in a food for sale in an amount of no more than 10 g/kg (1%) of each ingredient. Unapproved GM foods are not permitted in any amount.</p>
4.	<p>Requests FSANZ consider a strategy for providing suitable information on the iron content of meat analogue products containing soy leghemoglobin to the public and health professionals to assist people manage their iron intake when required for medical reasons. This may include people who suffer from haemochromatosis, or people with anaemia.</p>	QLD Health	<p>FSANZ considers that Impossible meat analogue products contain higher (and more bioavailable) iron levels than known meat analogue products on the market in Australia and New Zealand. As the submitter highlighted, inclusion of iron content in an NIP is not mandatory unless the manufacturer is making a nutrition content or health claim.</p> <p>FSANZ consulted with the applicant who advised that they do not currently make 'good source of iron' claims on their packaged products, but may do so in retail marketing and advertising. The applicant has confirmed they provide education material to their retail customers, this could include nutrition information specifying iron levels in the meat analogue product (and other technological and nutritional considerations – See section 4.3 of this report).</p> <p>FSANZ will liaise with interested jurisdictions to update existing consumer information on our website to include nutritional, science and technological aspects of meat analogue products generally (including some GM production processes and varying nutrient levels, such as iron, B12 and protein in meat analogue products) (see section 4.2 of this report).</p>

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). Amendments were made to the SD1, following the 2nd CFS, related to terminology (i.e. removal of reference to LegH Prep and substitution with ‘soy leghemoglobin preparation’ or ‘the Preparation’, to align with drafting terminology) and an additional reference was added to Section 2.3.4. This reference is an article recently accepted for publication by the applicant, summarising some of the data from the production strain.

2.2.1 Safety assessment

The toxicological assessment was 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 Preparation, a number of criteria have been addressed, including the safety of the *P. pastoris* host strain, novel proteins, toxicity 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. There are no microbiological concerns regarding pathogens in the Preparation.

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 Preparation 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. The Preparation was not genotoxic *in vitro* and did not cause adverse effects in short-term toxicity studies in rats. The No Observed Adverse Effects Level (NOAEL) of freeze-dried Preparation 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 the Preparation 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 the Preparation 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 the Preparation 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 intakes at the maximum proposed use level ranged between 20 – 70 for mean intakes 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 the Preparation 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 intake assessment which is likely to overestimate intakes over a long period of time.

As of March 2020, the applicant advised they had sold approximately 100,000,000 quarter-pound (113 g) servings of meat analogue products containing the Preparation. 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.

2.2.2 Nutrition assessment

The nutrition assessment considered structural and physicochemical data on soy leghemoglobin, and an in vitro study using an intestinal cell model that compared the bioavailability of iron from soy leghaemoglobin with bovine haemoglobin. The available data indicates that soy leghemoglobin is structurally similar to animal myoglobins and has similar physicochemical properties; it denatures at similar temperatures; is completely digested by the stomach enzyme pepsin; and the haem group is released from soy leghaemoglobin within the pH range that is found in the stomach. An in vitro study using intestinal cell model provided supporting evidence of bioavailability.

The nutrition assessment concluded that haem iron from soy leghemoglobin is expected to have similar bioavailability to haem iron from mammalian haem proteins (e.g. myoglobin present in muscle tissue). However, in the absence of in vivo studies, a quantitative comparison of haem iron bioavailability from soy leghemoglobin and other haem proteins is not possible. 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 the proposed 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 Upper Limits (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.

2.2.3 Risk and technical assessment conclusion

FSANZ considered the assessment of the Preparation, including the soy leghemoglobin, raised no public health and safety concerns associated with its use in meat analogue products at the proposed maximum level of 0.8% soy leghemoglobin in raw product.

3 Risk management

3.1 Regulation of soy leghemoglobin in the Code

Due to its production method, FSANZ assessed the Preparation containing soy leghemoglobin as a food produced using gene technology. This enabled an assessment of the residual *Pichia* protein and genomic DNA in the Preparation. In the approved draft variation, the definition and permission for the Preparation is provided in Schedule 26 of the Code, with its specification outlined in Schedule 3.

Due to its use as a source of iron, FSANZ assessed soy leghemoglobin as a permitted form of iron, a nutritive substance. This enabled an assessment of the bioavailability of iron in soy leghemoglobin. In the approved draft variation, the permission is provided in Schedule 17.

FSANZ concluded it was not necessary to complete a novel food assessment because:

- a GM production method is used for the manufacture of the soy leghemoglobin in the Preparation, so FSANZ assessed all components of the Preparation under Standard 1.5.2 – *Food produced using gene technology*;
- There is no requirement in the Code for a substance to be assessed or permitted as both a GM and novel food.
- This approach is consistent with other applications FSANZ has undertaken (i.e. A1155 – *2'-FL and LNnT in infant formula and other products*).

Some stakeholders consider soy leghemoglobin should be regulated as a food additive (flavouring) because it is regulated as such in some countries overseas. FSANZ acknowledges that the addition of soy leghemoglobin can provide a flavouring and colouring effect, similar to that of myoglobin. FSANZ has given significant consideration to this issue:

- Assessment of the GM and nutritive aspects of soy leghemoglobin ensured the safety, bioavailability and regulatory clarity of soy leghemoglobin in the Preparation, which resulted in permissions for a food produced using gene technology, and a permitted form of the mineral iron – a nutritive substance.
- The application referred to both the nutritional and flavouring functions of soy leghemoglobin; there was no reference to a colouring function.
- FSANZ therefore considered also assessing as a food additive (flavouring), noting it would result in three separate permissions for the one ingredient in the Code.
- The applicant's flavour permission was sought as part of the novel food permission (Section B.1, page 12 of the application). As discussed above, FSANZ did not undertake a novel food assessment so this section of the application was reviewed for relevant data and information, but not considered as part of the regulatory approach.
- Upon review of the Code, it was identified that regulation of soy leghemoglobin as a permitted flavouring substance would have had the unintended consequence of permitting soy leghemoglobin in all foods.
- FSANZ does not independently assess and regulate flavourings. Standard 1.1.2—2 defines 'permitted flavouring substances', and FSANZ determined that soy leghemoglobin does not align with paragraph a) – a list a of external publications for permitted flavourings, nor does it align with paragraph b) or c).
- Soy leghemoglobin can contribute flavour and colour to Impossible meat analogue products, without having to be regulated as such. Many substances added to food may have multiple functions such as nutritive, flavouring and/or colouring. FSANZ consider the regulatory approach to not regulate every function of soy leghemoglobin is appropriate and consistent with that used for several multi-function substances in

the Code. Most food ingredients, including nutritive substances could provide colour and flavour to food but that does not make them colours or flavouring food additives. Equally, several food additives such as calcium salts also contribute to the calcium content of food, but that does not make them nutritive substances.

- Additional permissions in the Code would not have provided any greater protection of public health and safety.

The proposed regulatory approach (GM and nutritive substance permissions) aligns with the structure of the Code and appropriately reflects the nature of soy leghemoglobin (produced through microbial fermentation of a GM yeast, and as a source of iron). The approved variation tightly regulates soy leghemoglobin in the Preparation for safety, and allows flexible use for its functions in the applicant's meat analogue products.

3.1.1 Permitted use levels of the soy leghemoglobin

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

- There is an absence of safety data and information for use 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%. Specifically, this relates to the haem iron in the soy leghemoglobin resulting in 'livery' or 'metallic' flavours that are off-putting to consumers 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 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 patties based on ultra-high performance liquid chromatography methodology. A confidential document appended to the application described the applicant's procedure for measurement of soy leghemoglobin concentration in Impossible meat analogue burger patties. FSANZ notes that test results on these products stored under various conditions exhibited high levels of consistency.

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 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 Impossible meat analogue products with enforcement agencies on a confidential basis.

The risk of products containing a mix of Impossible meat analogue product (containing soy leghemoglobin) and meat has been raised in submissions by some stakeholders. FSANZ understands this is not the intent of the applicant, who has intellectual property rights to prevent the misuse of their products. The applicant has confirmed it will not be supplying the Preparation containing soy leghemoglobin itself as an ingredient to any distributor or third party without a contractual arrangement, requiring it will be for use in meat analogue

products carrying the Impossible branding only. They have advised they will use lot numbers on purchase orders to create auditable records of the Preparation.

The issue of enforcing the permitted maximum use level in cooked product was raised in submissions. FSANZ has used the maximum use level of 0.8% soy leghemoglobin in the raw product and assumed 25% moisture loss during cooking to estimate the levels in the equivalent cooked product. In reality the levels in the cooked product are likely to vary based on the specific product, cooking method used and cooking times.

1. 100 g raw Impossible meat analogue product contains maximum 0.8 g soy leghemoglobin.
2. Assume 25% moisture loss¹² on cooking the product, and no loss of soy leghemoglobin.
3. $100 - 25 = 75$ g cooked product therefore contains maximum 0.8 g soy leghemoglobin, so that
4. 100g cooked product contains maximum 1.07 g soy leghemoglobin.

Expressed as an equation:

$$\begin{aligned} &\text{Max soy leghemoglobin (g) /100 g cooked product} \\ &= (0.8 \text{ g} \times 100) / (100 \text{ g} - 25 \text{ g}) = 1.07 \text{ g} \end{aligned}$$

Any use of soy leghemoglobin will therefore be controlled and monitored by the applicant and auditable by Australian and New Zealand enforcement agencies. Additionally, the applicant has agreed to share with enforcement agencies its methods of analysis for detecting soy leghemoglobin in meat analogue products on a confidential basis.

3.2 Labelling requirements

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

¹² For the purpose of this example the moisture loss during cooking for products containing soy leghemoglobin is assumed to be similar to the weight change from baking or frying beef mince and beef rissoles (-26%) and vegetable patties (-20%), as published in the [AUSNUT 2011-13 Food Recipe File](#) on the FSANZ website.

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 the soy leghemoglobin as an ingredient in a meat analogue product will 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 that produces soy leghemoglobin will be present in the meat analogue product. As noted in section 1.2 of this report, the applicant plans to sell their meat analogue products 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 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 (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.

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 will 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 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 will apply to meat analogue products containing soy leghemoglobin as an ingredient.

As noted in Section 3.2.4 above, the addition of soy leghemoglobin will 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 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 will 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 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 will 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 the regulatory measures

Based on its assessment, FSANZ's risk management conclusion is to permit and regulate the use of 'soy leghemoglobin' as a nutritive substance; and the 'soy leghemoglobin preparation' as a food produced using gene technology, in meat analogue products 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 'soy leghemoglobin preparation' as a food produced using gene technology by listing the Preparation with the same gene-gene donor source, and 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'.

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

Existing labelling requirements will apply to the soy leghemoglobin in the form of the Preparation, enabling consumers to make informed choices.

FSANZ has approved a draft variation to the Code at Attachment A, to give effect to the above. Consequential amendments have been added 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).

A1186 drafting and the review of A1155

FSANZ notes that the A1155 review was recently considered and accepted with amendments by the Forum. Attachments A and B of this report containing the draft variation and explanatory statement therefore remain as proposed. However this drafting relies on amendments made to the Code by A1155 in Schedules 3 and 26. A mock-up demonstrating how A1186 would be inserted into Schedules 3 and 26 in the event it is considered by the Forum before A1155 is gazetted has been prepared at Attachment C.

4 Risk communication

4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed a communication strategy to support the release of both calls for submissions in relation to this application. Subscribers and interested parties were notified about public consultation periods via the FSANZ Notification Circular. A media release and FSANZ's social media tools and Food Standards News were also used to raise awareness in the community regarding the opportunity for comment.

FSANZ sought submissions to its preliminary position in the 1st CFS from 20 December 2019 – 14th February 2020. 44 submissions were received.

FSANZ sought submissions to the proposed draft variation in the 2nd CFS from 6 August 2020 – 17 September 2020. 16 submissions were received.

FSANZ had regard to all submissions received for this Application.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. All comments are valued and contributed to the rigour of our assessment.

Targeted consultation

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

After reviewing submissions to the 2nd CFS, FSANZ did not consider further targeted consultation was warranted, as submitters did not provide any new evidence or substantiated arguments beyond what had been addressed previously. Questions or concerns on the draft variation were answered as part of submission responses, no changes were made.

4.2 FSANZ meat analogue product consumer information

FSANZ understands that meat analogue products are becoming more popular with consumers looking to reduce or eliminate their meat intake. New technologies are increasingly developed and/or used to produce them. FSANZ will liaise with interested jurisdictions to update existing consumer information on our website to include nutritional, science and technological aspects of meat analogue products generally (including some GM production processes and varying nutrient levels, such as iron, B12 and protein in meat analogue products). This may include a suggestion that individuals who have conditions such as soy allergies, or haemochromatosis (excessive iron storage in the body) to check labels for ingredients and nutrient levels; or if not available, ask at point of service or contact the manufacturer for necessary information.

4.3 Impossible education material to retail customers

When entering new markets, the applicant has informed FSANZ it provides its retail customers with product and education material. This covers the company and product overview, nutrition facts, ingredients, information on soy leghemoglobin (including that it is produced using genetic engineering), sustainability data, Kosher/Halal/ gluten free status, and sales data relevant to food service. A modified resource for the Australia New Zealand market could be developed.

4.4 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. Current patents held by the applicant are likely to restrict the sale of this ingredient beyond Impossible meat analogue products for the foreseeable future.

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 therefore not considered necessary.

5 FSANZ Act assessment requirements

5.1 Section 29

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

5.1.1 Consideration of costs and benefits

This analysis considers permitting the voluntary use of soy leghemoglobin in meat analogue products as a substance that is *used as a nutritive substance – iron*, and the Preparation (containing soy leghemoglobin) as a *food produced using gene technology*.

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. Based on FSANZ's risk assessment, including data and information reviewed at the 1st and 2nd CFS, FSANZ considers that no other realistic food regulatory measures exist.

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 Preparation to meat analogue products as proposed.

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 with the ability to purchase and sell Impossible branded meat analogue products containing soy leghemoglobin 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 analogue products. 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 meat analogue 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 meat analogue 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.

5.1.3 Other measures

There are no other measures (whether available to FSANZ or not) that 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

The relevant Standards apply in both Australia and New Zealand. There are no relevant New Zealand only 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 the Preparation containing soy leghemoglobin 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 will apply to soy leghemoglobin when added as an ingredient to meat analogue products, as discussed in section 3.2 of this report, which will provide adequate information to enable consumers make informed choice.

5.2.3 The prevention of misleading or deceptive conduct

FSANZ considers the application of the existing labelling requirements described in section 3.2 of this report to soy leghemoglobin addresses this objective.

5.3 Subsection 18(2)

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 in Impossible meat analogue products in some other countries, including in the US, Canada, Singapore, Hong Kong and Macau. 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 manufacturers can use to 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 the 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 guideline¹⁴. Currently, there is no other relevant policy guidance.

5.4 Conclusion

FSANZ has assessed application A1186, concluding soy leghemoglobin (in the form of the Preparation) raises no public health and safety concerns associated with use in meat analogue products, at the proposed maximum use level of 0.8% in raw product. 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.

FSANZ has gone beyond assessment of soy leghemoglobin by considering the applicant's meat analogue products and the potential for Australian and New Zealand consumers to be misled by meat analogue products (see above in section 3.2 and SD2). Additionally, FSANZ will liaise with interested Jurisdictions in updating consumer information on our website to include relevant information on meat analogue products in relation to key nutritional, science and technological considerations.

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 permitted form of a nutritive substance*, and the Preparation containing soy leghemoglobin (ii) *as food produced 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 and weighed all aspects of the assessment against the statutory requirements FSANZ has decided to approve the draft variation to the Code.

¹⁴ See [Communique](#)

6 References

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Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Mock-up of proposed drafting for Schedule 3 and Schedule 26
- D. List of submitters at 2nd CFS

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



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

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
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[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	<i>Pichia Pastoris</i> containing the gene for leghemoglobin c2 from <i>Glycine max</i>	<ol style="list-style-type: none">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.
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Attachment B – 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 (*Pichia pastoris*), in a soy leghemoglobin preparation to meat analogue products at levels not more than 0.8% weight for weight (w/w¹⁵) in raw product. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to the Code.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved 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 included a total of two public and one targeted 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 an eight week consultation period,

¹⁵ %'weight for weight' or %'w/w' means g/100 g.

after which the Authority undertook targeted consultation with interested Australian enforcement agencies and the New Zealand Ministry of Primary Industries

A second consultation was undertaken on the Authority's proposed draft variation to the Code on 6 August 2020 for a 6 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 a soy leghemoglobin preparation as a nutritive substance in meat analogue products, as proposed, is voluntary. In addition, permissions in the draft variation are likely to have only a minor impact on business and individuals because they are minor, deregulatory changes that allow 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—the soy leghemoglobin preparation, 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 *particular* 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, which is yet to be gazetted. 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

<i>Substance</i>	<i>Provision</i>
....
<i>Salmonella</i> 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) <i>Escherichia coli</i> K-12 containing the gene for alpha-1,2-fucosyltransferase from <i>Helicobacter pylori</i>	<ul style="list-style-type: none"> 1. May only be added to infant formula products 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 <i>Food Standards (Application A1155 – 2'-FL and LNnT in infant formula and other products) Variation</i> and ending 15 months after that date.
2 Lacto-N-neotetraose	(a) <i>Escherichia coli</i> K-12 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from <i>Neisseria meningitidis</i> and the gene for beta-1,4-galactosyltransferase from <i>Helicobacter pylori</i>	<ul style="list-style-type: none"> 1. May only be added to the following foods in combination with 2'-O-fucosyllactose that is permitted for use in infant formula products. 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 <i>Food Standards (Application A1155 – 2'-FL and LNnT in infant formula and other products) Variation</i> and ending 15 months after that date.
3 Soy leghemoglobin preparation	<i>Pichia pastoris</i> containing the gene for leghemoglobin c2 from <i>Glycine max</i>	<ul style="list-style-type: none"> 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 – List of submitters at 2nd CFS

List of submitters:

Government (4)

- Victorian Department of Health and Human Services, Victorian Department of Jobs, Precincts and Regions (the Victorian Departments) and PrimeSafe (joint submission)
- NZ Ministry for Primary Industries / Food Safety
- QLD Health
- SA Health

Industry (5)

- Impossible Foods (applicant)
- Australian Food and Grocery Council
- New Zealand Food and Grocery Council
- Grill'd
- Milky Lane

Not for profit organisations (2)

- Allergy and Anaphylaxis Australia
- Food Frontier AU

Consumer organisations (3)

- Friends of the Earth and GeneEthics (joint submission)
- GE Free NZ
- Grey Power Combined NZ

Individual submitters (2)

Australia

- JM Private

New Zealand

- MC Private