



20 December 2019
[106-19]

Call for submissions – Application A1186

Soy leghemoglobin in meat analogue products

FSANZ has assessed an Application made by Impossible Foods Inc. Pursuant to section 44 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). FSANZ now calls for submissions to assist further consideration of the Application.

For information about making a submission, visit the [information for submitters](#) page on our website.

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

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

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

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 14 February 2020

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

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

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Table of contents

TABLE OF CONTENTS.....	2
EXECUTIVE SUMMARY.....	3
1 INTRODUCTION	5
1.1 THE APPLICANT.....	5
1.2 THE APPLICATION	5
1.3 THE CURRENT STANDARDS	6
1.3.1 <i>Australia and New Zealand</i>	6
1.3.2 <i>International Regulations</i>	7
1.4 REASONS FOR ACCEPTING APPLICATION.....	8
1.5 PROCEDURE FOR ASSESSMENT	8
2 RISK ASSESSMENT	8
3 RISK MANAGEMENT	10
<i>Potential allergenicity soy leghemoglobin and LegH Prep</i>	10
<i>Dietary intake of iron</i>	10
3.1 REQUIRED PERMISSION OF USE OF SOY LEGHEMOGLOBIN IN THE FORM OF LEGH PREP	10
3.1.1 <i>Maximum permitted use level of soy leghemoglobin</i>	10
3.2 LABELLING REQUIREMENTS.....	11
3.2.1 <i>Statement of ingredients</i>	11
3.2.2 <i>Mandatory nutrition information</i>	11
3.2.3 <i>Voluntary representations</i>	11
3.2.4 <i>Declaration of certain substances</i>	11
3.2.5 <i>Labelling as ‘genetically modified’</i>	12
3.3 MINISTERIAL POLICY GUIDELINES.....	12
3.4 CONCLUSION	12
4 RISK COMMUNICATION	13
4.1 CONSULTATION	13
4.2 WORLD TRADE ORGANIZATION (WTO).....	13
5 FSANZ ACT ASSESSMENT REQUIREMENTS	13
5.1 SECTION 29.....	13
5.1.1 <i>Consideration of costs and benefits</i>	13
5.1.2 <i>Other measures</i>	15
5.1.3 <i>Any relevant New Zealand standards</i>	15
5.1.4 <i>Any other relevant matters</i>	15
5.2 SUBSECTION 18(1).....	15
5.2.1 <i>Protection of public health and safety</i>	15
5.2.2 <i>The provision of adequate information relating to food to enable consumers to make informed choices</i>	15
5.2.3 <i>The prevention of misleading or deceptive conduct</i>	15
5.3 SUBSECTION 18(2) CONSIDERATIONS	15
6 REFERENCES	16

Supporting document

The following document informed the assessment of this Application and are available on the FSANZ website:

[SD1 Risk and Technical Assessment Report](#)

Executive summary

Impossible Foods submitted an application to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of soy leghemoglobin¹ in the form of LegH Prep in meat analogue products (including the Impossible™ Burger, meatballs, sausages, and as fillings in buns and dumplings). The applicant intends to use soy leghemoglobin at levels not more than 0.8% weight for weight (w/w) in raw product. This is intended to replicate the nutrition (source of iron), flavour and aroma of myoglobin, which is an oxygen storing haem protein found in muscle tissue (Ordway and Garry, 2004)

Soy leghemoglobin is a component of a cell lysate preparation from a genetically modified (GM) yeast, *Pichia pastoris*. This yeast has been modified to express the leghaemoglobin gene from soybean (*Glycine max*) and other host proteins that support its expression. Leghaemoglobin is a globulin protein, containing an iron-bound haem B prosthetic group and is typically expressed in the root nodules of leguminous plants. Soy leghemoglobin is distributed into the food matrix via a liquid preparation called LegH Prep, which also contains proteins and genomic DNA from the *Pichia* production strain and has sodium ascorbate and sodium chloride added as stabilisers.

The applicant currently manufactures soy leghemoglobin in the form of LegH Prep for their meat analogue products in the United States (US) and intends to import these products into Australia and New Zealand as raw, frozen, packaged products. These products will be marketed to retailers (such as grocery stores) and caterers (such as fast food restaurants) for final sale to the general population. LegH Prep itself will not be sold in Australia or New Zealand, but as an ingredient in the applicant's raw form of meat analogue products.

Meat analogue products containing LegH Prep are currently regulated in the US for purchase in retail and catering outlets (up to 0.8% soy leghemoglobin (raw w/w)) and in Singapore (up to 0.45% soy leghemoglobin (raw w/w)). Based on permissions in the US and Singapore, the Hong Kong Centre for Food Safety has subsequently permitted the import and sale of meat analogue products containing soy leghemoglobin in Hong Kong and Macao.

FSANZ assessed soy leghemoglobin as a 'food produced using gene technology' rather than as a 'novel food' (both categories require assessment of similar data and information). Specifications were provided for the identity and purity of LegH Prep. The applicant provided data and information to allow FSANZ to assess soy leghemoglobin as a permitted form of iron.

FSANZ's risk and technical assessment (SD1) concluded that soy leghemoglobin in the form of LegH Prep is safe for human consumption at levels up to 0.8% soy leghemoglobin. The safety 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.

¹ FSANZ recognises that in Australia and New Zealand, the English spelling for 'haem' is more commonly used than 'heme', however the name 'soy leghemoglobin' is a product name used by Impossible Foods. FSANZ will hereafter use 'soy leghemoglobin', 'leghaemoglobin' and 'haem'.

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It is FSANZ's view that the applicant has provided sufficient data to support the stability of soy leghemoglobin in the food matrix. Based on a conservative dietary intake assessment that is likely to have overestimated dietary intakes for LegH Prep and iron, Australian and New Zealand consumers will not exceed the upper level of intake (UL) for iron.

The purpose of this 1st Call for Submissions (CFS) is to provide FSANZ's safety and technical assessment, and FSANZ's preliminary position based on the assessment and request input from interested stakeholders. Submissions received will inform FSANZ's decision whether to prepare a draft variation to the Code to permit the use of soy leghemoglobin in food or to reject the application.

Further public consultation will occur if, after consideration of submissions received in response to this 1st CFS, FSANZ decides to prepare a draft variation.

Based on its assessment, FSANZ's preliminary position of the preparation of a draft variation would appear warranted. Its assessment suggests that, if the use of soy leghemoglobin in meat analogue products is to be permitted, the most appropriate permission would be:

- as a *food produced using gene technology* derived specifically from the GM production strain *Pichia pastoris*
- with a maximum permitted use level of 0.8% (w/w) in raw product
- as a permitted form of iron
- with *identity and purity* specifications for LegH Prep.

Any such permission would be subject to the Code's existing labelling requirements which would assist consumers in making informed decisions. A food for sale that has a GM food ingredient would be labelled 'genetically modified' in conjunction with the ingredient name. This does not apply to foods intended for immediate consumption (such as fast food), however this information should be available to the consumer upon request.

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1 Introduction

1.1 The applicant

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

1.2 The application

In August 2019, Impossible Foods applied to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of soy leghemoglobin, produced by genetically modified (GM) yeast *Pichia pastoris* (*P. pastoris*) as a component in meat analogue products (including the Impossible™ Burger, meatballs, sausages, and as fillings in buns and dumplings). This yeast has been modified to express the leghaemoglobin gene from soybean (*Glycine max*) and other host proteins that support the expression of leghaemoglobin. Products containing soy leghemoglobin are intended for consumption by the general population aged 2 years and older.

Impossible Foods stated it produces soy leghemoglobin as a haem-containing ingredient to replicate the nutrition (source of iron), flavour and aroma of myoglobin, a haem-containing protein found in the muscle tissue of animals. Soy leghemoglobin is added to the applicant's meat analogue products in the form of LegH Prep, a liquid preparation containing up to 9% soy leghemoglobin with a protein purity of at least 65%. Other substances in LegH Prep will include residual *P. pastoris* cell components such as proteins and nucleic acids, and added stabilisers (e.g. sodium ascorbate and sodium chloride).

LegH Prep itself will not be sold to manufacturers or consumers, but as an ingredient in Impossible Food's final meat analogue products at not more than 0.8% w/w soy leghemoglobin in the raw product. This level is at the lower end of the myoglobin content of red meat (0.8–1.8%) (Texas A&M Institute, 2019). Impossible Foods have indicated that, to obtain flavouring profiles similar to meat, soy leghemoglobin levels currently used in their raw beef and pork meat analogue products are 0.45% and 0.25% respectively.

Impossible Foods plan to import their packaged meat analogue products into Australia and New Zealand as raw, frozen product for sale to retail outlets such as grocery stores and fast food restaurants and other caterers. The applicant is aware that all ingredients in the final meat analogue product need to be compliant with the Code.

The application sought to include soy leghemoglobin in the Code as a novel food (in Schedule 25)², a nutritive substance (source of iron), and food produced using gene technology (in Schedule 26). It also provided identity and purity specifications for LegH Prep (proposed for Schedule 3). FSANZ understands the applicant has applied for patents in Australia and New Zealand for the methods of production and specifications for their meat analogue products, their LegH Prep and soy leghemoglobin product³.

² FSANZ has since reviewed internal processes on how to assess applications pertaining to food produced using gene technologies. If an application related to a GM food, it will no longer be assessed as a 'novel food' under Schedule 25; instead it will be assessed as a food produced using gene technology. This does not preclude its approval also as a nutritive substance where relevant.

³ FSANZ searched for "impossible foods" on [New Zealand Intellectual Property Office](#) and [IP Australia](#) websites.

1.3 The current standards

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

Standard 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 in the form of LegH Prep meets the criteria for *food produced using gene technology* (section 1.1.2—2), as it is derived from an organism modified using gene technology (i.e. derived from a GM *P. pastoris* strain). If approved, express permission for soy leghemoglobin is required in accordance with Standard 1.5.2 – *Food produced using gene technology* (i.e. listed in Schedule 26) (see also section 1.3.1.2 below).

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* (section 1.1.2—12).

Section 1.3.2—3 specifies 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.*

Schedule S17—4 already permits addition of iron to meat analogues providing they meet the outlined 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 will be used as a source of iron, meat analogues containing soy leghemoglobin will need to meet these conditions. The total iron content of meat analogues is indirectly controlled by a 'maximum claim per reference quantity (maximum percentage RDI claim)' i.e. 30% RDI/100 g reference quantity. No additional 'maximum permitted amount per reference quantity' is set for iron. If soy haemoglobin is regarded as a permitted form of iron, it will need listing in Schedule S17—3.

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. Soy leghemoglobin in the form of LegH Prep is intended as a new ingredient in Australia and New Zealand food supply and since there are no specifications currently provided in the Code, a specification will be required in Schedule 3.

1.3.1.3 Labelling requirements

Paragraph 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 products to be labelled with a statement of ingredients.

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

Standard 1.2.8 generally requires food products to be labelled with nutrition information.

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 Schedule S26—3. The requirements imposed by section 1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer under subsection 1.2.1—8(1) and section 1.2.1—15 respectively. 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)).

1.3.2 International Regulations

1.3.2.1 United States

Impossible Foods obtained self-affirmed FDA GRAS status (GRN 737) in July 2018 to use soy leghemoglobin at levels up to 0.8% in its raw ground (minced) beef analogue products as a flavour optimiser. In addition, the applicant lodged a colour additive petition to the FDA in November 2018 to amend the colour additive regulations in 21 CFR part 73, 'Listing of Color Additives Exempt from Certification'. As shown on the FDA website⁴, this rule came into effect from 4 September 2019.

1.3.2.2 Singapore

The Agri-Food and Veterinary Authority (now the Singapore Food Agency) in August 2018 permitted the applicant's soy leghemoglobin as a food additive or ingredient in 'plant-based meat analogues' at levels up to 0.45% (w/w). The applicant provided documented permissions for soy leghemoglobin in Singapore as part of the Application (SFA, 2019). FSANZ are following up with the Singapore Food Agency to better understand the rationale behind permitting lower levels of soy leghemoglobin.

1.3.2.3 Hong Kong and Macao

The applicant indicated that soy leghemoglobin was respectively permitted in Hong Kong and Macao as a result of 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.

⁴ <https://www.regulations.gov/document?D=FDA-2018-C-4464-0002>

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

1.3.2.4 European Union

Impossible Foods lodged a request in October 2019 to market soy leghemoglobin produced from genetically modified *Pichia pastoris* with the European Food Safety Authority (EFSA)⁵ (Requestor member state – The Netherlands). At the time of writing, this application is currently under consideration as a GMO application Reg. 1829/2003.

1.4 Reasons for accepting application

The Application was accepted for assessment because:

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

1.5 Procedure for assessment

The Application is being assessed under a Major Procedure.

2 Risk assessment

FSANZ conducted a comprehensive assessment following 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.

In conducting the risk assessment of the soy leghemoglobin and the LegH Prep (see SD1), a number of criteria have been addressed, including the safety of the *P. pastoris* host strain, novel proteins, toxicity of the LegH Prep and a nutritional and dietary intake assessment. The safety assessment of the source organism and novel proteins concluded there were no public health and safety concerns. The source organism is a well characterised yeast with a recognised safe history of use for the production of food enzymes. It is neither pathogenic nor toxigenic.

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

The Applicant submitted *in vitro* genotoxicity studies in bacterial and mammalian cells and an oral toxicity study in rats. These studies are intended to confirm the outcome of the compositional and bioinformatic analysis conducted as a part of the safety assessment. No hazard was identified in the submitted studies. LegH Prep was not genotoxic *in vitro* and did not cause adverse effects in short-term toxicity studies in rats. The NOAEL of freeze-dried

⁵ For further information see [EFSA registration of questions webpage](#); Application number GMO-2019-0008; mandate number is M-2019-0132.

LegH Prep in a 28-day dietary toxicity study in rats was 1536 mg/kg bw/day, the highest dose tested. This dose corresponds to 1421 mg/kg bw/day TOS.

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

The margins of exposure (MOEs) between the NOAEL of 1421 mg/kg bw/day TOS in the rat oral toxicity study and estimated dietary exposures at the maximum proposed use level ranged between 20 – 70 for mean exposures and between 10 – 30 at the 90th percentile. At likely use levels, MOEs for mean and P90 estimated dietary intakes ranged between 40 – 130 and 20 – 60, respectively. These MOEs are not considered to be of concern given that; a sufficient body of knowledge exists on the safety of the organism (it is not pathogenic or toxigenic), the soy leghemoglobin and *Pichia* proteins will be digested like other dietary proteins and do not share any significant similarities to known allergens or toxins; and the conservative nature of the dietary exposure assessment which is likely to overestimate intakes over a long period of time.

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

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

The Applicant states that over 20 million servings of meat analogue products containing LegH Prep have been sold in the US since June 2016, and products are also sold in restaurants in Hong Kong, Macau and Singapore. FSANZ notes the Applicant has indicated there are no reports of adverse events from consumption of these products.

In conclusion, the assessment of soy leghemoglobin and the LegH Prep concluded that there are no public health and safety concerns associated with its use in meat analogue products at the proposed level of up to 0.8% soy leghemoglobin.

3 Risk management

Soy leghemoglobin, is proposed to be a new ingredient in the Australian and New Zealand food supply. The risk management response to matters raised by the risk assessment are as follows.

Potential allergenicity soy leghemoglobin and LegH Prep

The safety assessment of soy leghemoglobin of the residual *Pichia* proteins identified no allergenicity concerns. FSANZ is also not aware of any reported adverse reactions related to the consumption of the meat analogue products containing soy leghemoglobin, since being made available on the international market in 2016. However, FSANZ notes the soybean source of the leghaemoglobin and that foods derived from soybean require mandatory allergen warning labelling in Australia and New Zealand (see section 3.2.4 below).

Dietary intake of iron

The nutritional impact section of SD1 concluded that the bioavailability of haem iron from soy leghemoglobin was likely to be similar to myoglobin and haemoglobin in meat, noting that iron absorption is largely regulated in response to an individual's iron status. The applicant indicated that non-haem iron is contributed by other ingredients in its meat analogue products. This may also be the case for other meat analogues because addition of various forms of non-haem iron to these products is permitted by the Code. If so, the total iron content of meat analogues may be higher than red meat. However this does not raise concerns about health risk because the conservative and likely overestimated dietary intake assessment (see SD1; section 2.6) concluded that total iron intakes are below the UL for iron in all age/sex populations. Additionally, the level of iron claimed in 'analogues of meat' is limited by the Code in Schedule 17—4 *Maximum claim per reference quantity (maximum percentage RDI claim)*, which is likely a deterrent for other manufacturers to add high amounts of iron into their meat analogue products.

3.1 Required permission of use of soy leghemoglobin in the form of LegH Prep

FSANZ's assessment suggests that, if a draft variation is prepared to permit the use of soy leghemoglobin in the form of LegH Prep, the appropriate form of permission would be as a GM food and as a permitted form of iron, and with a specification for LegH Prep being included in Schedule 3 of the Code.

3.1.1 Maximum permitted use level of soy leghemoglobin

FSANZ's assessment also had regard to whether a maximum permitted use level should be established for soy leghemoglobin and if so, what would be the appropriate level.

In the absence of safety data and information for LegH Prep containing soy leghemoglobin levels above 0.8%, the imposition of a maximum permitted use level would appear warranted. Additionally, the application indicates palatability starts to be impacted at levels beyond 0.8% soy leghemoglobin. The applicant also claims 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). Because a permission in the Code may become generic in the future, FSANZ's preliminary view is that a maximum permitted use level should be set at no higher than the proposed maximum use level of 0.8%.

3.2 Labelling requirements

Existing mandatory requirements for the statement of ingredients, nutrition labelling and declarations of certain (allergenic) substances would apply to meat analogue products containing soy leghemoglobin. Further, existing claim requirements and conditions would apply if voluntary claims are made on these products.

3.2.1 Statement of ingredients

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 Schedule 10 – *Generic names of ingredients and conditions for their use*. There is no requirement for a statement of ingredients to be present on the label of a food for sale that is not required to bear a label.

FSANZ's preliminary view is that these generic requirements appear appropriate for the declaration of this ingredient in the statement of ingredients.

3.2.2 Mandatory nutrition information

Paragraph 1.2.8—6(1)(d)(ii) of Standard 1.2.8 – *Nutrition information requirements* requires the nutrition information panel (NIP) on a package of food to include the average quantity of protein for a serving of the food and a unit quantity of the food.

The addition of soy leghemoglobin as an ingredient, if permitted, would not trigger a mandatory declaration for iron in the NIP unless a claim requiring nutrition information (a nutrition content claim or a health claim) is made. However, if such a claim is made, the NIP must include a declaration about the presence of iron in accordance with subparagraph 1.2.8—6(1)(d)(iv).

3.2.3 Voluntary representations

As a result of the risk and technical assessment (SD1), FSANZ has concluded that soy leghemoglobin, if permitted, has the potential to be used as a source of iron. Use of soy leghemoglobin as an ingredient in the amount indicated by the applicant may meet the requirements for making a 'good source' nutrition content claim in relation to its iron content. The conditions for making such claims are set out in section S4—3 of Schedule 4 and other nutrition content claim requirements are set out in Standard 1.2.7 – *Nutrition, health and related claims*. Claims that directly or indirectly compare the vitamin or mineral content of a food with that of another food must not be made unless already permitted by the Code (section 1.2.7—9).

Food that meets the general claim conditions for making nutrition content claims about certain properties of food, may also be eligible to make one of the permitted general level health claims in section S4—5 of Schedule 4, subject to meeting other general level health claim requirements in Standard 1.2.7. 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 general level health claim.

3.2.4 Declaration of certain substances

In accordance with section 1.2.3—4 of Standard 1.2.3 – *Information requirements – warning statements, advisory statements and declarations*, if soy is present as an ingredient or as an

ingredient of a compound ingredient it must be declared on the label. If the food is not required to bear a label, the allergen information must be displayed in connection with the display of the food or provided to the purchaser on request (section 1.2.1—9 of Standard 1.2.1).

Food sold to a caterer in a package must include the soy declaration on the label, as required by sections 1.2.1—12 and 1.2.1—15 of Standard 1.2.1 – *Requirements to have labels or otherwise provide information*.

3.2.5 Labelling as ‘genetically modified’

As discussed in the risk and technical assessment (SD1), novel DNA and novel protein from genetically modified *P. pastoris* strain will be present in the final meat analogue product from the LegH prep ingredient.

A food for sale that has a genetically modified food ingredient, and is required to bear a label (for example, packaged frozen burger patties), would be required to be labelled ‘genetically modified’ in conjunction with the ingredient name. Similarly, information relating to foods produced using gene technology is required on labelling for food sold to a caterer.

Existing labelling provisions specify that food intended for immediate consumption that is prepared and sold from food premises and vending vehicles is exempt from GM food labelling requirements (see section 1.3.1 above).

However, paragraph 1.2.1—15(f) of Standard 1.2.1 requires information relating to foods produced using gene technology to be on labelling for food sold to a caterer. Subsection 1.1.2—2(3) of Standard 1.1.2 (Definitions used throughout the Code) defines ‘caterer’ to mean 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. Consequently, in relation to such food, a consumer may seek information about the food from the food business.

3.3 Ministerial Policy Guidelines

FSANZ had regard to the *Ministerial Policy Guideline for the fortification of foods with vitamins and minerals*⁶ in relation to soy leghemoglobin as a form of iron, in particular the potential for use of soy haemoglobin to contribute to nutritional equivalence of a substitute food, in this case, meat analogue for meat. FSANZ’s assessment is that permitting soy leghemoglobin for use as a source of iron brings the final meat analogue product closer to the primary counterpart meat by providing greater nutritional equivalence through the provision of both haem and non-haem iron.

3.4 Conclusion

FSANZ’s assessment is that consuming meat analogue products containing soy leghemoglobin at levels up to 0.8% poses no health or safety concerns to the Australian and New Zealand populations, and can provide an alternative dietary source of haem iron

Based on its assessment, and the considerations summarised above, FSANZ’s preliminary position is that preparation of a draft variation would appear warranted. The assessment also

⁶ <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-for-the-Fortification-of-Foods-with-Vitamins-and-Minerals>

suggests that, if the use of soy leghemoglobin in meat analogue products is to be permitted, the most appropriate permission would be:

- as a *food produced using gene technology* derived specifically from the GM production strain *Pichia pastoris*
- with a maximum permitted use level of 0.8% (w/w) in raw product
- as a permitted form of iron
- with *identity and purity* specifications for LegH Prep.

4 Risk communication

4.1 Consultation

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

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

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

4.2 World Trade Organization (WTO)

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

This issue will be fully considered at the next stage of the assessment. As explained above, FSANZ has yet to decide to prepare a proposed measure. Submissions received in response to this Call for Submissions will inform that decision. If FSANZ decides to prepare a proposed measure, public consultation must occur in relation to that measure, once prepared. If necessary, notification will be made at that point in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade (TBT) or Application of Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO members to comment on any proposed amendments.

5 FSANZ Act assessment requirements

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

5.1 Section 29

5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting genetically modified food that is voluntary (OBPR correspondence dated 24 November 2010, reference 12065).

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

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

FSANZ considers that no other realistic food regulatory measures exist, however information received may result in FSANZ arriving at a different outcome.

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

Industry

Approving this product will provide the applicant with the capacity to earn revenue from their innovation, in Australia and New Zealand. Australia and New Zealand businesses will be able to purchase and sell 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

Consumers may benefit from greater choice of foods, particularly greater choice of meat substitutes with potentially superior attributes if this product is approved. Soy leghemoglobin will be sold in the applicant's meat analogue products. The applicant is targeting their products at 'flexitarians', who they claim (on page 62 of the application) are looking for a "more ethical and environmentally friendly alternative meat products without compromising on attributes such as the taste and texture". This is likely to be a premium product so it is unlikely that it will become confused or substituted for meat in the short to medium term. Labelling of meat analogue products containing soy leghemoglobin that is sold packaged (e.g. frozen burger patties) would allow consumers wishing to avoid these products to do so. Existing consumer protections exist to protect consumers from it being substituted for meat and vice-versa.

Government

There may be a small cost to government in terms of monitoring and compliance to ensure the final products comply with the Code and food laws set in Australia and New Zealand as well as laws preventing misleading or deceptive commercial conduct.

5.1.1.2 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 likely outweighs the associated costs.

Additional information received from in response to this Call for Submissions, and any second Call for Submission on a draft variation, may enable FSANZ to undertake a more quantitative-based assessment of the associated wider costs and benefits in permitting soy leghemoglobin in meat analogue products. This will depend on the quality of data or information received in submissions and may result in FSANZ arriving at a different conclusion.

5.1.2 Other measures

At this stage FSANZ is not aware of any measures which would be more cost-effective than a food regulatory measure developed or varied as a result of the Application. FSANZ seeks comments on this assessment to inform its decision on preparation of draft variation.

5.1.3 Any relevant New Zealand standards

There are no relevant New Zealand Standards.

5.1.4 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 (SD1) which is summarised in section 2. The assessment concluded that there are no public health and safety concerns associated with permitting soy leghemoglobin (via LegH Prep) in meat analogue products at the requested level of up to 0.8%.

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

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

5.2.3 The prevention of misleading or deceptive conduct

The labelling requirements in section 3.2 would address this objective.

5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to assess this application. The applicant submitted a dossier of scientific studies as part of its application. Other relevant information including scientific literature, was also used in assessing the application.

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

Soy leghemoglobin is permitted for use and sold in Impossible Foods meat analogue products in some countries overseas, including in the US, Singapore, Hong Kong and Macao. An application is currently being considered by EFSA for permissions in the European Union. Permitting soy leghemoglobin at the requested level of up to 0.8%, would promote greater compatibility between domestic and overseas food standards for meat analogue products. The applicant's proposed specifications for LegH Prep are the same as those approved in other countries.

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

Permitting soy leghemoglobin in meat analogue products in the Code would support an internationally competitive 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**

The Policy Guideline for the Fortification of food with Vitamins and Minerals relies on the need for the mineral to be bioavailable to potentially support the nutritional adequacy of the local diet. Based on the assessment of bioavailability, FSANZ considers that the Policy Guideline has been met.

6 References

SFA (2019). Food Additives Permitted Under the Singapore Food Regulations. (28 May 2019). Singapore Food Agency (SFA). Available at: <https://www.sfa.gov.sg/legislation>

Texas A&M Institute (2019). Meat Science: Meat Color. College Station (TX): Texas A&M Institute. Available at: <https://meat.tamu.edu/ansc-307-honors/meat-color/> [Last accessed: 20 October, 2019]

Attachments

SD1 – Risk and technical assessment