



## Application A1186 Soy Leghemoglobin in meat analogue products

### Call for Submissions

#### Submission

#### Summary

NSW welcomes the opportunity to comment on Application A1186 - Soy Leghemoglobin in meat analogue products.

NSW understands FSANZ is considering soy leghemoglobin as a permitted form of vitamin and mineral (iron) and as a product of gene technology in meat analogue products.

NSW understands that the United States Food and Drug Administration amended its federal register to provide for the safe use of this same product as a colour additive in ground beef analogue products in 2019.

NSW provides comment or seeks further information and clarity in the second call for submissions on a number of issues concerning this application.

#### Clarity in the intent of the proposed amendment

NSW notes that FSANZ proposes to amend the Australia New Zealand Food Standards Code (the Code) to provide:

- Listing of soy leghemoglobin as food produced using gene technology - derived from GM strain of *Pichia pastoris* (schedule 26).
- To a maximum permitted limit of soy leghemoglobin 0.8% (w/w) in raw product.
- Soy leghemoglobin as a permitted form of iron under schedule 17.
- An identity and purity specification for soy leghemoglobin in Schedule 3.

NSW understands the net result of these changes would result in only soy leghemoglobin to a maximum concentration of 0.8% w/w in raw product, sourced from Genetically Modified (GM) *Pichia pastoris* (listed in schedule 26<sup>1</sup>) legally assuming the role of a 'nutritive substance'<sup>2</sup> (as a permitted source of iron - schedule

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<sup>1</sup> <https://www.legislation.gov.au/Details/F2019C00131>

<sup>2</sup> <https://www.legislation.gov.au/Details/F2017C00313>

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17-3<sup>3</sup>) in 'analogues of meat' (schedule 17- 4) becoming food for sale in Australia or New Zealand.

These permissions would be provided by Standard 1.3.2-3(a) of the Code with the permitted food additions provided in Standard 1.3.2-3(b). The identity and purity of the soy leghemoglobin sourced as described above would need to comply with the proposed specification for soy leghemoglobin in Schedule 3<sup>4</sup>.

If NSW assumptions on proposed drafting are correct, NSW considers this to be an appropriate approach to permit a unique substance such as soy leghemoglobin. Comments below are based on the above approach.

NSW seeks further information in the second call for submissions (CFS) on several additional matters associated with FSANZ's intended approach for amending the Code:

- The making of claims.
- The category of listing in Schedule 26 of the Code for Soy Leghemoglobin
- The listing of soy leghemoglobin as a source of iron in 'analogues of meat' given the large variety of products the applicant has listed.
- Labelling of food for sale containing soy leghemoglobin as GM.

*The making of claims*

NSW seeks further clarity in the second CFS on the operation and implications of claim conditions, particularly 'good source' claims as they would apply to this product. In particular whether a %RDI listing can be made in the Nutrition Information Panel for a 'good source' Iron nutrition content claim without breaching Standard 1.3.2-4 of the Code.

A 'good source' claim for Iron (schedule 4-3<sup>5</sup>) requires Iron to be listed in Schedule 1<sup>6</sup>, with a serve of the food containing at least 10% RDI. Schedule 1 provides that the RDI for Iron is 12mg and SD 1 in the 1<sup>st</sup> CFS<sup>7</sup> (pg. 22) provides that 100g of Impossible burger with 0.45% soy leghemoglobin contains 3.7mg of Iron per 100g.

This satisfies the 10% RDI threshold required. However Schedule 4-3 also provides that a claim may not be for more of a mineral than what is provided by Standard 1.3.2-3(c). This Standard references Schedule 17-3 and 17-4 of the Code where the category of food most appropriate for Soy leghemoglobin would be 'analogues of meat'. The limit for Iron claims provided in Schedule 17-4 in 'analogues of meat' is 3.5mg per 100g of reference quantity. Can FSANZ clarify in the 2<sup>nd</sup> CFS call for submissions whether the %RDI limit for a mineral claim in Schedule 17-4 is an absolute limit for all % RDI claims, including 'good source' claims, where the amount of a mineral present in a reference quantity is greater than the limit in Schedule 17-4?

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<sup>3</sup> <https://www.legislation.gov.au/Details/F2017C00328>

<sup>4</sup> <https://www.legislation.gov.au/Details/F2019C00729>

<sup>5</sup> <https://www.legislation.gov.au/Details/F2017C00711>

<sup>6</sup> <https://www.legislation.gov.au/Details/F2018C00960>

<sup>7</sup> [https://www.foodstandards.gov.au/code/applications/Documents/A1186\\_SD1.pdf](https://www.foodstandards.gov.au/code/applications/Documents/A1186_SD1.pdf)

NSW further queries whether the mandatory nature of listing %RDI for 'claims requiring nutritional content' (Standard 1.2.8-9<sup>8</sup>) then overcomes this possible conflict as claims are defined in Standard 1.1.2<sup>9</sup> as '*an express or implied statement, representation, design or information in relation to a food or a property of food which is not mandatory in this Code*'. It could be argued that declaration of the %RDI in the nutrition information panel in conjunction with a 'good source' nutrition content claim is not voluntary (Standard 1.2.8-9), meaning that % RDI listing in relation to 'good source' is no longer a claim. NSW seeks further clarity in the 2<sup>nd</sup> CFS on the operation and implications of claim conditions, particularly 'good source' claims as they would apply to product containing soy leghemoglobin.

#### *Schedule 26 listing*

NSW seeks clarification on how 'soy leghemoglobin' will be listed in Schedule 26 of the Code. The first CFS document suggests that the protein is not sourced from the soybean but from the roots of the plant. This seems to imply that a new commodity category may be required.

#### *Schedule 17-4 'analogues of meat'*

It is unclear to NSW if all the intended food products noted by the applicant (e.g. burger, meatballs, sausages, fillings in buns and dumplings<sup>10</sup> - 1<sup>st</sup> CFS pg. 3) will comply with the requirements for 'analogues of meat'. Schedule 17-4 as the commencing statement in this category provides that:

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

The term 'analogues of meat' is un-defined in the Code. NSW requests that FSANZ clarify in the 2<sup>nd</sup> CFS whether this terms adequately frames and restricts addition of product for sale containing soy leghemoglobin, and if it could be used to enforce sale of a food if it did not comply with this category in Schedule 17-4.

NSW also seeks FSANZ clarification in the 2<sup>nd</sup> CFS whether '5g of protein per serve of the food' is a qualifying limit for 'analogues of meat' or an upper limit.

#### *Labelling of products as sourced from genetically modified (GM) material*

NSW interpretation of Standard 1.5.2 concerning GM labelling are outlined below:

- all products containing soy leghemoglobin intended to be supplied into the Australian and New Zealand retail sector (e.g. supermarkets) for consumer purchase will be labelled as GM product for the purposes of Standard 1.5.2<sup>11</sup> of the Code.

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<sup>8</sup> <https://www.legislation.gov.au/Details/F2018C00944>

<sup>9</sup> <https://www.legislation.gov.au/Details/F2018C00912>

<sup>10</sup> <https://www.foodstandards.gov.au/code/applications/Documents/A1186%201st%20CFS%20report.pdf>

<sup>11</sup> <https://www.legislation.gov.au/Details/F2018C00169>

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- product containing soy leghemoglobin sold for catering purposes (e.g. to a fast food chain) for use as an ingredient in a food for sale provided to a consumer for immediate consumption (e.g. a burger) will not require GM labelling on the package of the food provided to the consumer. However, the outlet providing the food for sale to the consumer would need to provide this information to a consumer upon request.

### **Alignment of the permission proposed in the Code with the FDA listing in Code of Federal Regulations 73-520**

NSW has reviewed several documents submitted to the FDA by Impossible Foods:

- GRN 540<sup>12</sup> (GRAS permission status) and FDA response<sup>13</sup>
- GRN 737 (2<sup>nd</sup> filing for GRAS status)<sup>14</sup>
- FDA response of 'no questions' to GRN 737<sup>15</sup>
- Application to FDA from Impossible concerning declaration of Soy Leghemoglobin as a colour additive exempt from certification<sup>16</sup>
- Code of Federal Regulations (CFR) 73.520 (Soy Leghemoglobin listing)<sup>17</sup>

NSW notes that the permission listed in the CFR 73.520 is specific to the use of soy leghemoglobin in 'ground beef analogue products' as a colour additive.

NSW queries whether the proposed listing in the Code by FSANZ will have an equally specific scope of application as the most likely Schedule 17-4 category is 'analogues of meat'.

NSW notes the allergenicity data, toxicity data and dietary exposure assessment data provided by Impossible foods to the FDA in GRN 737 seems related to use of soy leghemoglobin (to a maximum concentration of 0.8% w/w) as an analogue in ground beef products. FSANZ is requested to contact the applicant to affirm whether this information is applicable to the addition of soy leghemoglobin to other products (e.g. dumplings, fillings in buns) as NSW cannot determine from its own review of GRN 737 whether the scope of product applications considered examined products such as dumplings, fillings in buns.

NSW notes the allergenicity study conducted in GRN 737 resulted in a finding of low allergenic potential. Notwithstanding this finding Impossible foods has indicated that it will put 'soy' on the label, and inform consumers that the product 'contains soy'<sup>18</sup>. NSW suggests a similar approach should be applied in the Code regarding the naming of 'analogue of meat' products containing soy leghemoglobin to ensure that soy sensitive consumers are appropriately informed.

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<sup>12</sup> [GRN No&order=540](#)

<sup>13</sup> [FDA response to GRN 540](#)

<sup>14</sup> <https://www.fda.gov/media/124351/download>

<sup>15</sup> <https://www.fda.gov/media/116243/download>

<sup>16</sup> [FDA additives-exempt-from-certification-soy-leghemoglobin](#)

<sup>17</sup> [CFR 73 520 Soy leghemoglobin](#)

<sup>18</sup> <https://www.fda.gov/media/124351/download>

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NSW further notes that 'soy protein concentrate'<sup>19</sup> is a major ingredient in the impossible burger marketed in the USA. Should soy leghemoglobin, as an ingredient in 'analogues of meat', be marketed in a similar fashion in the Australian and New Zealand markets, NSW expects that allergen declaration requirements of the Code would apply. NSW seeks FSANZ clarity on this matter in the 2<sup>nd</sup> CFS.

### Naming of products

NSW notes that some of the products the applicant intends to supply the market with have prescribed definitions in the Code or contain language that have defined terms - e.g. sausage and meatball.

Standard 2.2.1-2<sup>20</sup> of the Code defines sausage as a food that:

*(a) consists of meat that has been minced, meat that has been comminuted, or a mixture of both, whether or not mixed with other foods, and which has been encased or formed into discrete units; and*

*(b) does not include meat formed or joined into the semblance of cuts of meat.*

Meat is defined in this standard to mean 'the whole or part of the carcass or any of the following animals, if slaughtered other than in a wild state'...

The purpose of adding soy leghemoglobin to analogue products is to '*replicate the nutrition (source of iron), flavour and aroma of myoglobin*'<sup>21</sup>. This is taking the analogue market a step closer to true meat than currently available products as they resemble their meat based counterparts in shape only - not also in texture, flavour and aroma, and key nutrients such as iron.

NSW requests that the true source of products marketed as 'analogues of meat' containing soy leghemoglobin is made very clear on product packaging so consumers are aware of what products they are purchasing. This may require the drafting of Chapter 1 standards (e.g. Standard 1.1.1-13 (4)<sup>22</sup> and 1.2.2-2 (1)(b)<sup>23</sup>) to be considered so the potential for soy leghemoglobin containing products to be marketed or labelled as 'meatless meatballs' is avoided.

NSW recommends that FSANZ also consult with the ACCC regarding the naming and marketing of Impossible Foods products containing soy leghemoglobin as it intends to '*replicate the nutrition (source of iron), flavour and aroma of myoglobin*'. Myoglobin is a key functional protein in meat based products. A substitute protein should be appropriately declared to the purchasing consumer so they are appropriately informed as to the true source of the leghemoglobin, with any marketing representations targeting broader issues, e.g. '*more ethical and environmentally friendly alternative meat products*' (pg. 14, 1st CFS) appropriately examined to provide accurate information to purchasing consumers.

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<sup>19</sup> <https://faq.impossiblefoods.com/hc/en-us/articles/360018937494-What-are-the-ingredients->

<sup>20</sup> <https://www.legislation.gov.au/Details/F2016C00173>

<sup>21</sup> <https://www.foodstandards.gov.au/code/applications/Documents/A1186%201st%20CFS%20report.pdf>

<sup>22</sup> <https://www.legislation.gov.au/Details/F2020C00027>

<sup>23</sup> <https://www.legislation.gov.au/Details/F2015L00389>

## Ministerial Policy Guideline for fortification of foods with minerals and vitamins

The Ministerial Policy Guidelines (MPG)<sup>24</sup> for fortification with vitamins and minerals are relevant to Application 1186. Within this document, the voluntary fortification section is appropriate as soy leghemoglobin in meat analogues are being used as substitute's food to meat containing myoglobin.

The MPG also suggests that *'the fortification of a food, and the amounts of fortificant in the food, should not mislead the consumer as to the nutritional quality of the fortified food'*.

Review of the iron content of the Impossible burger in SD1 for the 1<sup>st</sup> CFS informs that it contains greater iron levels than the comparative beef burger. This presents a risk that general marketing surrounding the alternative choice may create a 'health halo' surrounding plant based alternatives. The applicant has suggested that 'flexitarians' who are claimed to be seeking a *'more ethical and environmentally friendly alternative meat products without compromising on attributes such as the taste and texture'* will be targeted by product marketing.

NSW seeks clarification from FSANZ in the 2<sup>nd</sup> CFS as to whether on-balance there is a possible risk of plant based alternatives containing soy leghemoglobin being marketed in a way that may suggest nutritional superiority compared to counterpart meat products.

A review of beef burger composition compared to the Impossible burger informs, that in some instances, there is little difference in total energy content between the two<sup>25</sup> (Impossible burger – 887 kJ per 100g and lean beef burger – 907 kJ per 100g). However as both are manufactured products energy values will vary dependent on inputs. There are also other beef burgers on the market with significantly lower kJ per 100g (peppercorn beef burger extra lean – 622 kJ per 100g<sup>26</sup>). However the Australian dietary guidelines consider all commercial burgers (irrespective of source) as discretionary foods<sup>27</sup>. It would therefore seem prudent to ensure that the marketing and/or any potential claims that may surround plant based alternative burgers does not artificially create a 'health halo' that is not commensurate with the status of commercial burgers as discretionary foods in the Australian dietary guidelines. This would seem relevant to the marketing context of plant based alternatives products being sold into the catering supply chain (i.e. for use in burgers sold at fast food outlets). NSW requests that FSANZ explore this matter in the 2<sup>nd</sup> CFS.

For retail supply chains (i.e. supermarkets), NSW considers that the impossible burger may be marketed in Australian and New Zealand supermarkets in a manner similar to Gelson's market<sup>28</sup> in the USA, where the blended product containing soy

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<sup>24</sup> [Minister Policy for fortification with Vitamins and Minerals](#)

<sup>25</sup> <https://www.cnet.com/news/is-the-impossible-burger-healthier-than-beef/>

<sup>26</sup> [peppercorn-beef-burger-extra-lean](#)

<sup>27</sup> <https://www.eatforhealth.gov.au/food-essentials/discretionary-food-and-drink-choices>

<sup>28</sup> [impossible-burger-launching-stores-first-gelsons-markets/2343853001/](#)



leghemoglobin would be presented to consumers in a manner similar to minced meat. Further review of the website of Gelson's market provides recipes for the use of impossible burger in lasagne<sup>29</sup> and meatballs<sup>30</sup> so it would appear that minced meat is a relevant comparator product for the sale of the impossible burger in retail outlets (e.g. supermarkets).

NSW requests that FSANZ explore in the 2<sup>nd</sup> CFS the nutritional similarity of minced meat products compared to the impossible burger with due regard to the content of the MPG.

### **Synthetic foods policy guideline**

At a meeting of Australian and New Zealand Food ministers in November 2019<sup>31</sup> the issue of plant based foods providing an alternative to animal-derived products was discussed. Ministers recognised the value of the meat and dairy sector to the Australian and New Zealand, diet and economy, but also recognised the growing value of the alternative products sector and agreed that both have a place in the market for consumers.

Arising from this discussion, Ministers asked the Food Regulation Standing Committee (FRSC) for its consideration of regulatory and labelling issues relating to 'synthetic' foods, with a view to developing a policy guideline to adequately differentiate 'synthetic' animal products from their natural or conventional equivalents. Given Ministerial interest in this area, FSANZ is suggested to take a conservative approach to the drafting of permissions in the Code for Application 1186.

### **Communications material for plant based meat analogues**

Plant based meat analogues are a fast-growing market segment sold in a range of forms: ready to cook, as components of ready to reheat and eat meals, sold refrigerated or frozen and in kits of dry ingredients to be rehydrated and made into burger patties etc. Some canned products are also available.

These foods are moist protein foods and the hazard of microbial growth would be expected to be the same as in traditional animal protein foods although the initial contamination levels and the range of organisms present may be different from those found in traditional animal protein foods.

NSW suggests that FSANZ together with other food regulators consider the preparation of appropriate communications material concerning this growing category to advise consumers, caterers and retailers on the importance of proper cooking and handling to minimise the risk of food poisoning from harmful pathogenic bacteria that may be present in the supply chain.

Our rapid search of literature and regulatory web-pages indicated that there have been no local or international reports of outbreaks of foodborne illnesses attributed to

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<sup>29</sup> [impossible--lasagna--made-with-the-impossible--burger-.html](#)

<sup>30</sup> [impossible--meatball--subs--made-with-impossible--burger-.html](#)

<sup>31</sup> [Forum-Communique\\_15\\_November\\_19.pdf](#)

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these food products. US and European recall and withdrawal records show occasional recalls and withdrawals for meat analogues or other vegan foods, due to undeclared allergens and errors with date labelling. To date these types of foods have not been represented in Australian food recalls and withdrawals.

**ENDS**

**The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.**

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