The Soil & Health Association of New Zealand Inc.

Submission to the FSANZ

Application A1186 Soy Leghemoglobin

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1.0 Soil and Health consider that the application for A1186 Soy Leghemoglobin which is a mixture referred to as 'LegH Prep'[1] is inadequate to ensure a high standard of public health protection. It does not contain sufficient information to ensure activities relevant to the approval will fulfill the Objectives of the Food Standards Australia New Zealand Act 1991.

1.1. The report ignores the health impact of the final product. The LegH Prep has been specifically developed to be an ingredient in an ultra-processed convenience food product.
1.2. Nutrition is cherry-picked despite the product being positioned as a meat substitute. Equivalent iron is not substantially equivalent as other nutritional parameters are ignored in the application.
1.3. The contaminant profile[2] from herbicides contained in the retail product, which unprocessed meat does not contain has been ignored.
1.4. Differing health effects relating to the potential for endocrine disruption at different life stages has been ignored.
1.5. There are no long-term dietary studies – a 28-day study restricts consideration on health effect and the longer dietary studies are reasonable to scientifically risk assess long term (chronic) effects.
1.6. The chronic toxicological parameters relating to immunotoxicity, carcinogenicity, oxidative stress, as well as endocrinological effects are not clearly published.
1.7. 90-days dietary study must be supplied, including endocrinological test results, for the risk assessment to be scientifically appropriate to assess health risk:
    - OECD Test Guideline (TG) 408 – repeated dose 90-day oral toxicity study – *(Updated in 2018)*

1.8. Due to the scientific knowledge gaps and the deficiencies, and with particularly consideration of the commercial outcome of the approval of LegH Prep – the potential for a commercial product that the applicant intends to be considered a staple dietary product in the New Zealand and Australian diet - the Soil and Health Association of New Zealand propose that the LegH Prep (A1186) application should be declined.

[1] Soy leghemoglobin derived from genetically modified yeast Pichia pastoris, residual P. pastoris (yeast) proteins, & suitable stabilizers (e.g., sodium ascorbate & sodium chloride). Impossible Foods. Application to Amend the Australia & New Zealand Food Standards Code. A1186. https://www.foodstandards.gov.au/code/applications/Documents/A1186%20Executive%20Summary.pdf

[2] Food Standards Australia New Zealand Act 1991. S.19 (5)b

1.9. We emphasise that it is critical the repeated dose 90-day oral toxicity study is included in the submission, and the endocrinological endpoints submitted for public consultation.[3] We are aware this will be supplied from a laboratory selected and financed by the applicant, Impossible Foods.

2.0 Precautionary Principle. Soil and Health acknowledge that the Food Standards Australia New Zealand Act 1991 legislation carries no obligation for decision-makers to use the precautionary principle or take a precautionary approach in decision-making in the public interest.

3.0 Soil and Health note that section 18 of the FSANZ must have regard for the following when developing regulatory measures:

> (1) The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:
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> > (a) the **protection of public health** and safety; and
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> > (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
> >
> > (c) the prevention of **misleading** or deceptive conduct.
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> (2) In developing or reviewing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:
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> > (a) the need for standards to be based on risk analysis using the **best available scientific evidence;**

4.0 Food Standards Australia New Zealand Act Section 18. Soil and Health have concern that the current report/call for submissions reports reflects a regulatory environment that is not available to fulfil the objectives of s.18 due to extensive data gaps. We have the following concerns:

4.1. The current application may be misleading as it ignores the final formulation and acts in favour of the applicant at the publics expense.

4.2. The risk assessment excludes the best available scientific evidence as it has excluded a wide range of important considerations relevant to long term chronic exposures through the diet.

4.3. Current procedures and activities may be at risk of undermining consumer confidence in regulatory activities of the FSANZ and may therefore undermine the objectives of the Act.s.3 (a).

4.4. The narrow scope of consideration retains important scientific knowledge and data outside consideration, limiting data that may inform the public in the matter of the potential health risk of both the LegH Prep but also the final ultra-processed product. This narrow scope may undermine the objectives of the Act s.3(c).

4.5. The practice of directing the public's attention to the decisions of weaker regulatory environments (such as the United States) does not serve the public interest nor protect public health.

5.0 Endocrine gaps and gender specific health effects. The transparent publication of endocrine sensitive endpoints would reflect a scientific and evidence-based approach to human health protection and does not

[3]OECD GUIDELINE FOR THE TESTING OF CHEMICALS 408 (2018) Repeated Dose 90-day Oral Toxicity Study in Rodents. https://www.oecd.org/env/ehs/testing/Revision%20TG%20408%202018.pdf

compromise commercial confidentiality agreements. Of significant concern are apparent data gaps concerning potential endocrine effects:

5.1. Gender specific hormone related effects have not been discussed and appear to be overlooked.[4]

5.2. The potential for an altered estrogenic profile is ignored. Soy product has varying benefits at varying ages and the risk that endocrine disrupting hormonal action might be more detrimental for infants and children has not been discussed despite being scientifically plausible as a dietary risk.[5]

5.3. There is no information notifying the public whether the OECD 407 and 408 test guidelines were followed:

5.3.1. OECD Test Guideline (TG) 407 Repeated Dose 28-Day Oral Toxicity Study in Rodents - *Updated with Parameters for Endocrine Effects*

5.3.2. OECD Test Guideline (TG) 408 – repeated dose 90-day oral toxicity study - *Updated in 2018 to include endocrine sensitive endpoints*

5.3.3. We note that 407 only requires 10 animals (five of each sex) while 408 is stastically stronger as it requires 20 animals (ten of each sex)

5.4. OECD 407 (updated) and 408 (2018) test guidelines may not have been followed as there is no reference to the endocrine-sensitive endpoints in the publicly available data, nor the differences of effect in each sex.:

5.4.1. TG 407 requires

- Weight and histopathology of hormone-dependant tissues:
  - male and female reproductive tracts – and thyroid and pituitary
- Thyroid hormones (others not feasible)
- Sperm and estrous parameters

5.4.2. TG 408 requires: thyroxine (T4), triiodothyronine (T3), thyroid stimulating hormone (TSH) and thyroid gland weight, which are responsive to thyroid pathway perturbation (2). In addition, serum total cholesterol, low-density lipoproteins (LDL) and high-density lipoproteins (HDL) should also be determined as levels of these parameters are directly controlled by thyroid hormone action and contribute (with other thyroid endpoints) to evidence of thyroid effects.

5.4.3. It is important to recognise that the 90-day study requires a toxic response data by sex and dose level as chronic health effects are frequently gender specific.

6.0 Ultra-processed convenience food. Soil and Health consider this current application does not adequately reflect the obligations in law of the FSANZ to protect health. It is apparent that the scope of consideration is overly narrow and as a result cannot protect public health as consumers will be exposed to a fully formulated product that includes the LegH Prep mixture:

6.1. The final products consist of an ultra-processed products intended as a convenience food.
6.2. The commercial products are intended as a meat analogue product.
6.3. The product will be imported as a full formulation, it will not be produced in New Zealand
6.4. The products contain a large proportion of genetically modified soy and the nutritional assessment does not consider the entire exposures from the retail product.

[4] Vahter M et al 2007. Implications of gender differences for human health risk assessment and toxicology. *Environmental Research.* 104:1;70-84

[5] Patisaul, HB. Endocrine disruption by dietary phyto-oestrogens: impact on dimorphic sexual systems and behaviours. The Proceedings of the Nutrition Society. 76:2;130-144

6.5. Nutrition appears cherry-picked, for example, iron is considered but not B vitamins, the salt profile of the final product and the health benefits of these factors are ignored.
6.6. The products are presented as substantially equivalent to meat and the discussion in the application indicates that FSANZ considers the ingredient a substitute food to a dietary staple.
6.7. Risk to infants and children from regular consumption as a meat replacement is not considered.

7.0 90-day dietary studies should study the formulated retail product. Best available scientific evidence would look at the complete exposure of the final formulated product that, is considered to be safe for a human to consume regularly over a lifetime. The data supplied is inadequate to establish this.

7.1. One rat month is equivalent to 3 human years.[6]
7.2. A 28-day dietary rodent study is insufficient to gauge chronic toxicological and endocrinologic risk.
7.3. The minimum study supplied should be a 90-day dietary study. This has not been supplied.
7.4. Because this product is intended as a substitute for dietary protein lifetime (2 year) dietary studies should also have been supplied.
7.5. We consider 90-day studies at a minimum should be supplied both for the LegH Prep *and* the final formulated soy burger soy leghemoglobin derived from genetically modified yeast Pichia pastoris, residual P. pastoris (yeast) proteins, and suitable stabilizers (e.g., sodium ascorbate and sodium chloride).

8.0 Contaminants from dietary exposure. Best available scientific evidence would consider the contaminant profile of genetically engineered soy.

8.1. Risk assessment must consider contaminants.[7]
8.2. Naturally grown animal meat does not contain the same high residues of herbicides that are contained in soy and this is reflected in the maximum residue levels permitted in these products.[8]
8.3. 93% of soy grown is genetically modified.[9]
8.4. These Impossible Burger has been tested in the United States and glyphosate-based herbicides residues were detected.[10] It is not unforeseen that it will include the residues of other herbicides approved to be applied on genetically modified soy, in addition to the heavy metals and petrol compounds[11] used in these formulations.
8.5. Genetically modified soybeans can be imported into New Zealand for human consumption, including dicamba, glyphosate and 2,4D[12] The combinatory toxicity should be assessed as contaminants.

9.0 Misleading cost-benefit analysis. The cost-benefit analysis has not accounted for the fact that this product will be treated by the consumer as a substitute food and will be marketed as mentioned by FSANZ as a food for 'flexitarians' that will regard the food as safe as meat. The cost-benefit analysis is too narrow in scope to accurately ensure the objectives of the Act. Where has the following been cost-benefit analysis been undertaken?

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[6] Sengupta P. 2013 The Laboratory Rat: Relating Its Age With Human's. *International Journal of Preventive Medicine.* 4:6;624-630
[7] Food Standards Australia New Zealand Act 1991. S.19 (5)b
[8] http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/en/
[9] http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx
[10] Health Research Institute Laboratories. Report Number S0004900- 20190506 https://bit.ly/2vz6Shu
[11] Defarge, N., de Vendômois, J., & Séralini, G. (2018). Toxicity of formulants and heavy metals in glyphosate-based herbicides. Toxicology Reports, 156-163
[12] Current GM applications and approvals (August 2019)
https://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx

8.1. Analysis of the increased exposures to salt as a result of a dietary transition to these products
8.2. Analysis of the reduced B vitamins and amino acids as a result of a dietary transition to these products – particularly if the product is inferred to be substantially equivalent to meat.
8.3. Analysis of the increased exposures to estrogenic compounds as a result of a dietary transition to these products, with consideration that hormone disruption is a major factor in modern chronic disease.

9.0 Misleading: Substantial Equivalence. We express concern that the substantial equivalence moniker is strongly inferred and is likely to be interpreted by the public as a claim. We consider this approximates a message to the public that Impossible ultra-processed foods are as safe and healthy as unprocessed meat.

11.0 Misleading: Greater toxicity of the formulation. To ensure public safety, the full formulation of the product that will be exposed to consumers must be tested as per the intended consumption.

12.0 Misleading: Scientific knowledge gaps. The failure to consider the cumulative nutritional, toxicological and estrogenic profile of the final product amounts to a failure to utilise the best available evidence. Similarly the lack of long term studies regarding both the LegH Prep nor the final formulated product have the result that the product cannot be claimed as safe for a lifetime of public consumption, from infancy till death. These gaps are not discussed in the public arena, and so may have the result of the public believing that these products are risk assessed using the best available scientific evidence.

13.0 Soil and Health submit in a sceptical manner as it is rare that public health related submissions to the FSANZ result in a decision that is altered to reflect submitted concerns; or that addresses existing deficiencies to ensure future risk assessment is more rigorous and acts in favour of public health and the public interest.

14. We submit this application in an environment of increasing chronic health conditions, where years of life lost to chronic health conditions are increasing; chronic health conditions are occurring at younger and younger ages; and infants and children increasingly presenting with significant comorbidities.