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Ms Clare Bleakley
President
GE Free NZ
E: president@gefreenz.org

Dear Ms Bleakley

I refer to your request, dated 24 December 2019 under the *Freedom of Information Act 1982* (FOI Act) to Food Standards Australia New Zealand (FSANZ) seeking documents and information regarding Application A1186.

Your request

Your request sought the following in relation to Application A1186.

1. All report on the long term animal feeding studies that was conducted on the soy leghemoglobin,
    a. On animals
    b. On humans
2. The journal they were published in?
3. Levels of microbiological contaminants in the liquid?
4. Levels of fermentation substrates, production strain, and processing aids in the liquid
5. Levels of Heavy metals in the liquid?
6. DNA fragments from the process?
7. Allergen feeding studies and
8. Any studies to show if GE DNA fragments are absorbed into the blood stream?
9. Safety studies on children eating it?
10. Safety studies on elderly, sick eating it.
11. Evidence that the denatured protein will not harm consumers?
12. Confirmation that the imported liquid and the end product containing the Soy leghemoglobin protein will be labelled?

Application A1186 seeks an amendment to the *Australia New Zealand Food Standards Code* (the Code) to permit a specific soy leghemoglobin (which is in the form a liquid concentrate). FSANZ is proceeding with your request on the basis that it relates specifically to Application A1186 and to the specific soy leghemoglobin (or 'the liquid') which is the subject of that Application.

I note your advice that you have received the A1186 Call for Submission, which was released publically on 20 December 2019.

In terms of part 12 of your FOI request, I understand that you advised that, after receiving and reviewing the A1186 Call for Submissions and its supporting document, you are now satisfied that the information sought under Part 12 is provided in the Call for Submission.

You consider that this part of the request has been addressed. FSANZ therefore is also proceeding on the basis that part 12 of your FOI request is withdrawn.

Timeframe for a decision

Your FOI request must be decided by close of business on 23 January 2020. Thank you for agreeing under section 15AA of the FOI Act to the extension to 28 January 2020 to enable us to process your FOI request. As discussed, we were closed for the Christmas holiday period and many of the relevant staff were also absent on annual holidays.

FOI decision maker

I am an officer authorised under subsection 23(1) of the FOI Act to make decisions in relation to your FOI request.

Documents identified

No documents were identified that matched parts 1, 7, 8, 9, and 10 of the FOI request.

As FSANZ does not hold any documents that match part 1 of the FOI request, it also does not hold any documents that match part 2 of that request.

As explained below, parts 3, 4, 5, 6 and 11 of the FOI request sought the provision of information, not documents. The FOI Act only provides a right of access to existing documents.

Decision

I have decided to refuse your request for access to documents relating to parts 1, 7, 8, 9 and 10 of the FOI request under section 24A of the FOI Act.

Parts 2, 3, 4 5, 6 and 11 of your FOI request did not seek access to documents and therefore is out of scope for the purposes of the FOI Act.

Please note that most of the information sought in Parts 2, 3, 4 5, 6 and 11 of your FOI request is publically available. Please see the attachment to this letter which explains where and how you can access this information quickly to enable you to prepare a submission in relation to Application A1186.

Material taken into account

In making my decision, I had regard to:

a. the terms of the FOI request;

b. relevant provisions in the FOI Act;

c. the Guidelines published by the Office of the Australian Information Commissioner under section 93A of the FOI Act (the Guidelines); and

d. advice received from FSANZ officers responsible for processing and assessing Application A1186 and from FSANZ staff responsible for managing FOI requests received by FSANZ.

Reasons for decision

Section 24A – Refusal if documents cannot be found

Subsection 24A(1)(b)(i) of the FOI Act allows refusal of an FOI request if the agency is satisfied the requested document cannot be found or does not exist or has not been received.

An email was sent to all FSANZ staff on 8 January 2020 advising them of the request and asking them to identify and locate all relevant documents. Advice was also sought from the FSANZ officers responsible for processing and assessing Application A1186. These checks confirmed that FSANZ does not hold any documents that match the description of parts 1, 7, 8, 9, and 10 to your request.

In terms of part 1 to the request, it is noted that Application A1186 states that 28-day feeding studies in rats were undertaken for the purposes of preclinical toxicological testing and to corroborate safety. The results of these studies, which are not long term studies, are summarised in Application A1186. Reports of these feeding studies were not requested by or provided to FSANZ.

No long term animal or human feeding studies were sought by or provided to FSANZ for the purposes of Application A1186.

Similarly, none of the studies listed in parts 7, 8, 9 and 10 of your FOI request were sought by or provided to FSANZ for the purposes of Application A1186.

Nor have any such studies been generated by FSANZ.

As FSANZ does not hold any documents that match part 1 of the FOI request, it also does not hold any documents that match part 2 of your request.

Based on the above, I am satisfied that no documents could reasonably be found as matching parts 1, 2, 7, 8, 9, and 10 of the FOI request. Accordingly, I have decided to refuse access under section 24A of the FOI Act.

Request for information, advice or an opinion – out of scope

Parts 2, 3, 4, 5, 6, 11 and 12 of your request asked to be provided with advice or information, not documents held by FSANZ.

The FOI Act only provides a right of access to documents (see, for example, section 11 of that Act). This right is limited to documents that already exist. The Act does not require an agency such as FSANZ to create a new document to satisfy an FOI request (see Guideline 2.33 of the Guidelines). This means that the FOI Act does not provide a general right to request, and be provided with information, advice or an opinion. The right is also limited to documents that exist at the time the FOI request was made (see Guideline 2.34 of the Guidelines).

Part 12 of the request has been withdrawn (see above) as your query has been addressed to your satisfaction in the Call for Submission.

Part 2 of the request has been considered above.

The information sought in parts 3, 4 (with the exception of "levels of processing aids in the liquid;), 5, 6 and 11 of the FOI request is publically available. It is detailed in the Application A1186 Call for Submissions and/or Supporting Document 1 – the risk and technical assessment report – which are available on the FSANZ website. Please see the attachment to this letter which explains how and where you can access this information.

No information was sought by or provided to FSANZ for the purpose of Application A1186 in relation to the 'levels of processing aids in the liquid' (part 4 of the request).

Providing the requested information to you administratively

I understand that your FOI request was made for the purposes of assisting you to prepare a submission in response to the A1186 Call for Submissions. Therefore, to assist you prepare your submission, FSANZ staff have prepared the attachment to this letter which sets out where and how you can access the information sought in your FOI request.

Your review rights

If you are dissatisfied with my decision or the searches we did to locate any documents related to your request, you may apply for internal review or Information Commissioner review of the decision. We encourage you to seek internal review as a first step as it may provide a more rapid resolution of your concerns.

Internal review

Under section 54 of the FOI Act, you may apply in writing to the CEO, Food Standards Australia New Zealand for an internal review of my decision. You should send your request by email to FOI@foodstandards.gov.au . The internal review application must be made within 30 days of the date of this letter.

Where possible please attach reasons why you believe review of the decision is necessary. The internal review will be carried out by another officer within 30 days.

Information Commissioner review

Under section 54L of the FOI Act, you may apply to the Australian Information Commissioner to review my decision. An application for review by the Information Commissioner must be made in writing within 60 days of the date of this letter, and be lodged in one of the following ways:

online:	https://forms.business.gov.au/aba/oaic/foi-review-/
email:	enquiries@oaic.gov.au
post:	GPO Box 2999, Canberra ACT 2601
in person:	Level 3, 175 Pitt Street, Sydney NSW

More information about Information Commissioner review is available on the Office of the Australian Information Commissioner website. Go to www.oaic.gov.au/freedom-of-information/foi-reviews.

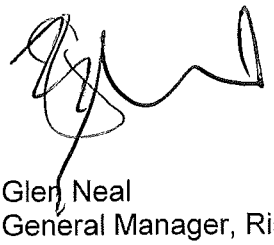
Further information

The contact officer for this matter is:

Mary Jordan
FOI Coordinator
Ph: +61 2 6271 2222
Email: FOI@foodstandards.gov.au

Please contact Ms Jordan if you require further information.

Yours sincerely



Glen Neal
General Manager, Risk Management and Intelligence
FOI Delegate

28 January 2020

Incl/ Attachment

ATTACHMENT - FOI GE FREE NZ A1186 – WHERE TO FIND THE REQUESTED INFORMATION TO ASSIST YOUR SUBMISSION

1. ***All report on the long term animal feeding studies that were conducted on the soy leghemoglobin,***

    a. ***On animals***
    b. ***On humans***

Details of feeding studies are provided as part of the main A1186 Application document (see Section C.4 *Toxicology data*). An assessment of this information is provided in the SD1 (see Section 2.4 *Toxicological assessment of LegH Prep*).

2. ***The journal they were published in?***

The feeding studies we have been provided and have assessed are published. They are publically available. You may access them from the websites noted below.

- Fraser RZ, Shitut M, Agrawal P, Mendes O, Klapholz S (2018) Safety Evaluation of Soy Leghemoglobin Protein Preparation Derived From *Pichia pastoris*, Intended for Use as a Flavor Catalyst in Plant-Based Meat. Int J Toxicol 37: 241-262 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5956568/)

- Jin Y, He X, Andoh-Kumi K, Fraser RZ, Lu M, Goodman RE (2018) Evaluating potential risks of food allergy and toxicity of soy leghemoglobin expressed in *Pichia pastoris.* Mol Nutr Fod Res 62:e1700297 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5813221/)

3. ***Levels of microbiological contaminants in the liquid?***

FSANZ is assuming that, by "the liquid", you are referring to the LegH preparation. Details of microbiological contaminants in this preparation is presented in the main A1186 Application document (see Section B.6 *Specifications*). A summary is also provided in the SD1 (see Section 2.1.3 *LegH Prep specifications*).

4. ***Levels of fermentation substrates, production strain, and processing aids in the liquid***

An outline of the manufacturing process, including the raw materials and processing aids, is provided in the main A1186 Application document (see Section B.4 *Manufacturing Process*).

Levels of the production strain in the LegH preparation is discussed in the main A1186 Application document (see Section B.4.4 *Fermentation and Recovery Processes* and Section B.5 *Information on the Impurity Profile*).

A summary of the FSANZ assessment of the manufacturing process is provided in the SD1 (see Section 2.7 *Manufacturing process*).

5. ***Levels of Heavy metals in the liquid?***

Details of heavy metal contaminants in the LegH preparation are presented in the main main A1186 Application document (see Section B.6 *Specifications*). You may also access this information from the summary which is provided in the SD1 (Section 2.1.3 *LegH Prep specifications*).

6. DNA fragments from the process?

FSANZ assumes this question refers to the presence of DNA in the LegH preparation.

Details are provided in the main A1186 Application document in Section B.4.2.4 *History of Use* and Section C.5.1 *Origins and History of Use.*

Please also note the summary of information provided in the SD1 (Section 2.7 *Manufacturing Process – Presence of novel DNA in the final product*).

7 to 10 – Studies and Evidence

You asked for the following 'as soy hemoglobin has not been in the animals or human food chain before as a GE or natural product':

7. *Allergen feeding studies and*
8. *Any studies to show if GE DNA fragments are absorbed into the blood stream?*
9. *Safety studies on children eating it?*
10. *Safety studies on elderly, sick eating it.*
11. *Evidence that the denatured protein will not harm consumers?*

Please see:

- the main A1186 Application document in Section C.4 *Toxicological Data,* and Section C.6 *Allergenicity*;
- the following Appendices of the A1186 Application:

  - Appendix VI *Structural comparison of plant hemoglobins and animal myoglobins*
  - Appendix VIII *Expert opinions on the safety of soy leghemoglobin and Pichia pastoris*
  - Appendix X *In vitro pepsin digestibility study/*

  These Appendices are available in the A1186 Call for submissions section of the FSANZ website and as listed separately above for ease of reference.

- SD1 – the technical and risk assessment, in particular:

  - Section 2.3 *Characterisation of the novel proteins*,
  - Section 2.4 *Toxicological assessment*,
  - Section 2.5 *Nutritional assessment* and
  - Section 2.6 *Dietary assessment*

Labelling

You requested confirmation that the imported liquid and the end product containing the Soy leghemoglobin protein will be labeled. Please see Section 3.2 *Labelling requirements* of the A1186 Call for Submissions for details regarding labelling.