

27 August 2019
[92-19]

Administrative Assessment Report – Application A1186

Soy leghemoglobin in meat analogue products

<p>Date received: 19th July 2019 Date due for completion of administrative assessment: 9th August 2019 Date completed: 9 August 2019</p>		
<p>Applicant: Impossible Foods Inc, the United States</p>		<p>Potentially affected standards:</p> <p>Schedule 26 Schedule 3 Schedule 17</p>
<p>Brief description of Application: To allow for the use of soy leghemoglobin derived from <i>P.pastoris</i> as a source of iron, aroma and flavour in meat analogue products.</p>		
<p>Procedure: Major</p> <p>Reasons why: The assessment will require a complex scientific and technical assessment and is likely to require significant stakeholder engagement and management.</p>	<p>Estimated total hours: 1503</p> <p>Reasons why: This application requires risk assessment and risk management input from several disciplines. The project is also likely to require significant stakeholder engagement and involve the development of a comprehensive community communications strategy.</p>	<p>Provisional estimated start work: early-September 2019</p>

Decision

<p>Application accepted</p> <p>Date: 9 August 2019</p>
--

Has the Applicant requested confidential commercial information status?

Yes ✓

What documents are affected?:

Appendix III Details of the Manufacturing Process

Appendix IV Internal Methods of Analysis

Has the Applicant provided justification for confidential commercial information request?

Yes ✓

Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together?

No ✓

Charges

Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant?

Yes ✓

If yes, indicate the reason:

Impossible Foods will not sell their soy leghemoglobin ingredient to other food manufacturers, or directly to consumers for use in recipes. The soy leghemoglobin will be used as an ingredient in meat analogue products that are manufactured only by Impossible Foods.

Due date for fees: 06 September 2019

Does the Applicant want to expedite consideration of this Application?

No ✓

Application Handbook requirements

Which Guidelines within the Part 3 of the *Application Handbook* apply to this Application?

3.1.1, 3.3.3, 3.5.1, 3.5.2

Is the checklist completed?

Yes ✓

Does the Application meet the requirements of the relevant Guidelines?

Yes ✓

Does the Application relate to a matter that may be developed as a food regulatory measure, or that warrants a variation of a food regulatory measure?

Yes ✓

Is the Application so similar to a previous application or proposal for the development or variation of a food regulatory measure that it ought not to be accepted?

No ✓

Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?

Yes ✓

If yes, indicate which Procedure:

Major

Other Comments or Relevant Matters:

Nil

Consultation & assessment timeframe

Proposed length of public consultation periods:

1st call for submissions – 8 weeks

2nd call for submissions – 6 weeks

Proposed timeframe for assessment:

'Early Bird Notification' due: mid-September 2019 (13th)

Major Procedure:

Commence assessment (clock start)	early-September 2019
Completion of assessment	late November 2019
Public comment	early December–early February 2020
Preparation of draft food regulatory measure	mid-May 2020
Public comment	mid-May–late June 2020
Board to complete approval	early-September 2020
Notification to Forum	late-September 2020
Anticipated gazettal if no review requested	late November 2020