

25 October 2019
[100-19]

Administrative Assessment Report – Application A1190

2'FL in infant formula and other products

<p>Date received: 3 Sept 2019 Date due for completion of administrative assessment: 24 Sept 2019 Date completed:</p>		
<p>Applicant: Jennewein Biotechnologie Consultant: Ramboll US Corporation</p>		<p>Potentially affected standard/s: Standard 2.9.1 Standard 2.9.3 Schedule 3 Schedule 26 Schedule 29</p>
<p>Brief description of Application: To permit 2'-fucosyllactose (2'-FL), produced by microbial fermentation using genetically modified <i>Escherichia coli</i> (<i>E. coli</i>) strains, in infant formula products and Formulated Supplementary Foods for Young Children (FSFYC)</p>		
<p>Procedure: General Level 5</p> <p>Reasons why: This is a complex application, based on anticipated technical and risk levels. However, as it follows A1155 and does not contain substantially new or different data or information, and stakeholder issues are likely to align with those raised for A1155, a general application is appropriate.</p>	<p>Estimated total hours: 1150</p> <p>Reasons why: This application involves adding a new substance to a limited range of foods and requires a complex pre-market approval.</p>	<p>Provisional estimated start work: Mid October 2019</p>

Decision

<p>Application accepted</p> <p>Date: 24 September 2019</p>
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Has the Applicant requested confidential commercial information status?

Yes No

What documents are affected?

- Appendix E
- Appendix K
- Appendix R
- Appendix S-W

Has the Applicant provided justification for confidential commercial information request?

Yes No

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

Yes No

Charges

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

Yes No

If yes, indicate the reason:

Jennewein has patented their production technology to synthesise their brand of 2'-FL. Any manufacturers looking to use the same production methods would have to enter a commercial agreement with Jennewein.

Approval of this application would provide Jennewein access to the Australian, New Zealand and international markets for the sale of 2'-FL to manufacturers of infant formula products and FSFYC. Exclusivity would apply to Jennewein's branded 2'-FL product for a period of 15 months.

Due date for fees: 22 October 2019

Does the Applicant want to expedite consideration of this Application?

Yes No – is paid

Application Handbook requirements

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

3.1.1 – General requirements

3.3.3 – Substances Used for Nutritive Purpose

3.5.1 – Foods produced using Gene Technology

3.6.2 – Special purpose foods – Infant formula products

3.6.3 – Special purpose foods – Other foods

Is the checklist completed?

Yes No

Does the Application meet the requirements of the relevant Guidelines?

Yes No

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 No

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?

Yes No

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

✓Yes No

If yes, indicate which Procedure:

Major

Consultation & assessment timeframe

Proposed length of public consultation period:

8 weeks

Proposed timeframe for assessment:

9 months (mid Oct 2019–mid July 2020)

General Procedure:

Commence assessment (clock start)	23 October 2019
Completion of assessment & preparation of draft food reg measure	Early Feb 2020
Public comment	Early Feb – late Mar 2020
Board to complete approval	Mid-June 2020
Notification to Forum	Late June 2020
Anticipated gazettal if no review requested	Late Aug 2020