

**25 October 2019**

**[100-19]**

**Administrative Assessment Report – Application A1190**

2’FL in infant formula and other products

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| **Date received:** 3 Sept 2019  **Date due for completion of administrative assessment:** 24 Sept 2019  **Date completed:** | | |
| **Applicant:** Jennewein Biotechnologie  **Consultant:** Ramboll US Corporation | | **Potentially affected standard/s:**  Standard 2.9.1  Standard 2.9.3  Schedule 3  Schedule 26  Schedule 29 |
| **Brief description of Application:**  To permit 2’-fucosyllactose (2’-FL), produced by microbial fermentation using genetically modified *Escherichia* *coli* (*E*. *coli*) strains, in infant formula products and Formulated Supplementary Foods for Young Children (FSFYC) | |
| **Procedure:**  General Level 5  **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. | **Estimated total hours:**  1150  **Reasons why:**  This application involves adding a new substance to a limited range of foods and requires a complex pre-market approval. | **Provisional estimated start work:**  Mid October 2019 |

***Decision***

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| **Application accepted**  **Date: 24 September 2019** |

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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***

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| **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***

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| **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***

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| **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 |