

**3 August 2021**

**165-21**

**Administrative Assessment Report –Application A1233**

2′-FL from new GM source for infant formula

1. **Application details**

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| **Date received:** 18 June 2021  **Date due for completion of administrative assessment:** 9 July 2021  **Date completed:** 5 July 2021 | | |
| **Applicant:**  FrieslandCampina Ingredients | | **Potentially affected standard:**  Schedule 26  Schedule 3 |
| **Brief description of Application:**  To permit 2′-fucosyllactose (2′-FL), produced by genetically modified *Escherichia coli* K-12, in infant formula products. | |
| **Procedure:**  General 2 | **Estimated total variable hours:**  380 hours  **Reasons why:**  Will involve: an assessment of the risk to safety of average complexity; and an assessment of risk management measures of average complexity; | **Estimated start date:** early August 2021 |

1. **Decision**

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| **Application accepted**  **Date**: 9 July 2021  **If fees for ECCB are not received, date of rejection:** 7 August 2021 |

1. **Additional matters**

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| **Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together?**  Yes  **Details:** The applicant has requested a period of exclusivity |

1. **Charges**

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| **Does FSANZ consider that the application confers an exclusive capturable commercial benefit (ECCB) on the Applicant?**  Yes  **Reason:**  Applicant has requested exclusivity for their branded product Aequival® 2'-FL  **Due date for fees:** 6 August 2021 |

1. **Assessment against FSANZ Act 1991 requirements**

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| **Subsection 26(2)** |
| **(a) 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 |
| **(b) Is the Application so similar to a previous application or proposal for the development or variation of a food regulatory measure that it should not be accepted?**  No |
| **(c) Are there any other matters relevant to the decision whether to accept or reject the application?**  No |

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| **Does the application meet each of the following criteria required by subsection 22(2)?** |
| 1. **The application is in writing**   Yes |
| 1. **The application is in the form specified in guideline 3.1.1 of the Application Handbook**   Yes |
| **(c) Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?**  Yes  **Indicate which Procedure:**  General |
| **Other Comments or Relevant Matters:**  Nil |

1. **Consultation & assessment timeframe**

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| **Proposed length of public consultation periods:**  6 weeks |
| **Proposed timeframe for assessment**  ‘Early Bird Notification’ due: 13 August 2021  General Procedure:  Commence assessment (clock start) early-August 2021  Completion of assessment & preparation of draft food reg measure late-October 2021  Public comment early-November to mid-December 2021  Board to complete approval late-April 2022  Notification to Forum late April 2022  Anticipated gazettal if no review requested late-June to early-July 2022 |