

**3 August 2021**

**165-21**

## **Administrative Assessment Report –Application A1233**

### **2'-FL from new GM source for infant formula**

#### **1. Application details**

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

#### **2. Decision**

<b>Application accepted</b> <b>Date:</b> 9 July 2021 <b>If fees for ECCB are not received, date of rejection:</b> 7 August 2021
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#### **3. Additional matters**

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

<b>Does FSANZ consider that the application confers an exclusive capturable commercial benefit (ECCB) on the Applicant?</b> Yes <b>Reason:</b> Applicant has requested exclusivity for their branded product Aequival® 2'-FL <b>Due date for fees:</b> 6 August 2021
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## 5. Assessment against FSANZ Act 1991 requirements

<b>Subsection 26(2)</b>
<b>(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?</b> Yes
<b>(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?</b> No
<b>(c) Are there any other matters relevant to the decision whether to accept or reject the application?</b> No

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

## 6. Consultation & assessment timeframe

### 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

