

9 September 2024
306-24

Administrative Assessment Report –Application A1312

2'-FL from GM *Escherichia coli* BL21 in infant formula products

1. Application details

<p>Date received: 30 July 2024 Date due for completion of administrative assessment: 20 August 2024 Date completed: 20 August 2024</p>		
<p>Applicant: Synaura Biotechnology (Shanghai) Co., Ltd.</p>		<p>Potentially affected Schedule 26 Schedule 3</p>
<p>Brief description of application: Application to amend the Australia New Zealand Food Standards Code to permit a new genetically modified source of <i>Escherichia coli</i> BL21 for the production of 2'-Fucosyllactose (2'-FL) for use as a nutritive substance in infant formula products.</p>		
<p>Procedure: General Level 2</p>	<p>Maximum total variable hours: 290 hours</p> <p>Reasons why: Will involve an assessment of the risk to safety of average complexity and an assessment of risk management measures of less than average complexity.</p>	<p>Estimated start date for assessment: Early September 2024</p>

2. Decision

<p>Application accepted</p> <p>Decision Date: 20 August 2024</p> <p>If fees for ECCB are not received, date of rejection: 17 September 2024</p>
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3. Consultation & assessment timeframe

Proposed length of public consultation periods:
6 weeks

Proposed timeframe for assessment
9 months

'Early Bird Notification' due: 24 September 2024

General Procedure:

Commence assessment (clock start)	early September 2024
Public comment	early Jan to mid Feb 2025
Board to complete approval by	early June 2025
Notification to Food Ministers' Meeting (FMM)	mid June 2025
Anticipated gazettal if no review requested	late August 2025