

13 August 2025
350-25

Administrative Assessment Report – Application A1336

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

1. Application details

Date received: 19 June 2025		
Date due for completion of administrative assessment: 11 July 2025		
Date completed: 9 July 2025		
Applicant: Synaura Biotechnology (Shanghai) Co., Ltd.		Potentially affected standard/s or schedule/s: Schedule 3 Schedule 26
Brief description of application: To permit a new genetically modified source of <i>Escherichia coli</i> BL21 (DE3) for the production of 2'-fucosyllactose (2'-FL) for use as a nutritive substance in infant formula products.		
Procedure: General Level 2	Maximum total variable hours: 290 hours 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.	Estimated start date for assessment: July 2026

2. Decision

Application accepted Decision Date: 09 July 2025

3. Consultation & assessment timeframe

Proposed length of public consultation periods:	
6 weeks	
Proposed timeframe for assessment	
Notification date: 13 August 2025	
<u>General Procedure:</u>	
Commence assessment (clock start)	mid July 2026
Public comment	early Nov to mid Dec 2026
Board to consider approval	mid March 2027
Notification to Food Ministers' Meeting (FMM)	late March 2027
Anticipated gazettal if no review requested	mid June 2027