

23 September 2025
359-25

Administrative Assessment Report – Application A1340

2'-FL from GM *Escherichia coli* BL21 (gene donor: *Akkermansia muciniphila*) for use as a nutritive substance in infant formula products

1. Application details

Date received: 12 August 2025		
Date due for completion of administrative assessment: 2 September 2025		
Date completed: 29 August 2025		
Applicant: Suzhou Yixi Biotech Co., Ltd.		Potentially affected schedules: Schedule 3 Schedule 26 Schedule 29
Brief description of application: To permit GM <i>Escherichia coli</i> BL21 (gene donor: <i>Akkermansia muciniphila</i>) for the production of 2'-FL for use as a nutritive substance in infant formula products.		
Procedure: General 2	Maximum total variable hours: 290 hours Reasons why: Will involve an assessment of safety risk of average complexity and an assessment of risk management measures of less than average complexity.	Estimated start date for assessment: Early October

2. Decision

Application accepted Decision Date: 29 August 2025 If fees for ECCB are not received, date of rejection: 26 September 2025

3. Consultation & assessment timeframe

Proposed length of public consultation periods:

6 weeks

Proposed timeframe for assessment

Notification due: 3 October 2025

General Procedure:

Commence assessment (clock start)	Early October 2025
Public comment	Mid January – Late February 2026
Board to consider approval	Mid June 2026
Notification to Food Ministers' Meeting (FMM)	Late June 2026
Anticipated gazettal if no review requested	Mid September 2026