

15 August 2024 300-24

Administrative Assessment Report – Application A1308

A1308 - 2'-FL from GM Escherichia coli W in infant formula products

1. Application details

Date received: 29 June 2024

Date due for completion of administrative assessment: 19 July 2024

Date completed: 17 July 2024		
Applicant: Kyowa Hakko Bio Co., Ltd		Potentially affected schedules: Schedule 3 Schedule 26 Schedule 29
Brief description of application: Application to amend the Australia New Zealand Food Standards Code to permit a new genetically modified source organism <i>Escherichia coli</i> W for the production of 2'-Fucosyllactose (2'-FL) in infant formula products.		
Procedure: General Level 2	Maximum total variable hours: 380 hours	Estimated start date for assessment: Mid-August 2024
	Reasons why: Will involve an assessment of the risk of safety of average complexity and an assessment of risk management measures of less than average complexity.	

2. Decision

Application accepted

Decision Date: 17 July 2024

3. Consultation & assessment timeframe

Proposed length of public consultation periods:

4-6 weeks

Proposed timeframe for assessment

General Procedure:

Commence assessment (clock start) Mid August 2024

Public comment Early Dec 2024 – mid Jan

2025

Board to complete approval by

Notification to Food Ministers' Meeting (FMM)

Anticipated gazettal if no review requested

Late April 2025 Mid May 2025 Late July 2025