

11 February 2025
328-25

Administrative Assessment Report – Application A1324

3-fucosyllactose as a nutritive substance in infant formula products

1. Application details

<p>Date received: 20 December 2024 Date due for completion of administrative assessment: 20 January 2025 Date completed: 16 January 2025</p>		
<p>Applicant: Glycom A/S</p>		<p>Potentially affected schedules: Schedule 3 Schedule 26 Schedule 29</p>
<p>Brief description of application: To permit the voluntary addition of 3-fucosyllactose (3-FL), a human-identical milk oligosaccharide (HiMO) produced using a genetically modified source organism, <i>Escherichia coli</i> K-12 in infant formula products.</p>		
<p>Procedure: General Level 4</p>	<p>Maximum total variable hours: 520 hours</p> <p>Reasons why: The application involves the addition of a new substance to a limited range of foods and requires a complex pre-market approval.</p>	<p>Estimated start date for assessment: February 2025</p>

2. Decision

<p>Application accepted</p> <p>Decision Date: 16 January 2025</p> <p>If fees for ECCB are not received, date of rejection: 15 February 2025</p>

3. Consultation & assessment timeframe

Proposed length of public consultation periods: Six weeks	
Proposed timeframe for assessment	
'Early Bird Notification' due: 21 February 2025	
<u>General Procedure:</u>	
Commence assessment (clock start)	Early February 2025
Public comment	Early May–Mid June 2025
Board to consider approval	Mid September 2025
Notification to Food Ministers' Meeting (FMM)	Late September 2025
Anticipated gazettal if no review requested	Early December 2025