

19 January 2023
226-23

Administrative Assessment Report –Application A1265

A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt for use as nutritive substances in infant formula products

1. Application details

<p>Date received: 22 November 2022 Date due for completion of administrative assessment: 13 December 2022 Date completed: 13 December 2022</p>		
<p>Applicant: Glycom A/S</p>		<p>Potentially affected standards or schedules:</p> <ul style="list-style-type: none"> • <i>Standard 2.9.1:</i> Infant formula products • <i>Schedule 29—5:</i> Infant formula products — substances permitted as nutritive substances • <i>Schedule 3:</i> Identity and purity • <i>Schedule 26:</i> Food produced using gene technology (of microbial origin)
<p>Brief description of Application:</p> <p>To permit the voluntary use of four human-identical milk oligosaccharide (HiMO) ingredients produced by microbial fermentation, alone or in combinations, as nutritive substances in infant formula products (IFP) namely:</p> <ul style="list-style-type: none"> ○ Mixture of 2'-fucosyllactose (2'-FL) and difucosyllactose (DFL) (“2' FL/DFL”); ○ Lacto-<i>N</i>-tetraose (LNT); ○ 6'-Sialyllactose (6'-SL) sodium salt; and ○ 3'-Sialyllactose (3'-SL) sodium salt. <p>The four HiMO ingredients are produced from the same genetically engineered <i>Escherichia coli</i> (<i>E. coli</i>) K-12-derived platform strain as Glycom’s 2'-FL and LNnT which is already authorised for use in Australia and New Zealand.</p>		
<p>Procedure: General [Level 5]</p>	<p>Maximum total variable hours: 828 hours</p> <p>Reasons why: This Application involves adding four new substances to a limited range of foods and requires a complex pre-market approval.</p>	<p>Estimated start date for assessment: Mid-January 2023</p>

2. Decision

Application accepted

Decision Date: 13 December 2022

If fees for ECCB are not received, date of rejection: 16 January 2023

3. Consultation & assessment timeframe

Proposed length of public consultation period:

Six weeks

Proposed timeframe for assessment

'Early Bird Notification' due: 23 January 2023

General Procedure:

Commence assessment (clock start)

Mid-January 2023

Public comment

Late May to Mid-July 2023

Board to complete approval*

Early October 2023

Notification to Food Ministers' Meeting (FMM)

Mid-October 2023

Anticipated gazettal if no review requested

Late December 2023