

**2 October 2025**  
**361-25**

## **Administrative Assessment Report – Application A1339**

2'-FL, 3-FL, LNT, 3'-SL, and 6'-SL from GM *Escherichia coli* BL21 for use as nutritive substances in infant formula products

### **1. Application details**

<b>Date received:</b> 1 August 2025		
<b>Date due for completion of administrative assessment:</b> 22 August 2025		
<b>Date completed:</b> 29 August 2025		
<b>Applicant:</b> Chr. Hansen A/S		<b>Potentially affected schedules:</b>  Schedule 3  Schedule 26  Schedule 29
<b>Brief description of application:</b>  To permit the voluntary use of 2'-FL, 3-FL, LNT, 3'-SL, and 6'-SL, alone or in combination, as nutritive substances in infant formula products. The nutritive substances ingredients are derived from various genetically modified <i>Escherichia coli</i> BL21 strains.		
<b>Procedure:</b>  General Level 5	<b>Maximum total variable hours:</b>  658 hours  <b>Reasons why:</b>  This Application seeks permission to add five new substances to a limited range of foods at different levels, requiring a complex assessment for pre-market approval.	<b>Estimated start date for assessment:</b>  Late September 2025

### **2. Decision**

<b>Application accepted</b> <b>Decision Date:</b> 28 August 2025 <b>If fees for ECCB are not received, date of rejection:</b> 25 September 2025
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### 3. Consultation & assessment timeframe

<b>Proposed length of public consultation periods:</b> 6 weeks	
<b>Proposed timeframe for assessment</b> <b>Notification due:</b> 2 October 2025 <u>General Procedure:</u> Commence assessment (clock start) Public comment Board to consider approval Notification to Food Ministers' Meeting (FMM) Anticipated gazettal if no review requested	
	Late September 2025 Early January – Mid February 2026 Mid June 2026 Late June 2026 Mid September 2026