



12 January 2018
[36-18]

Administrative Assessment Report – Application A1155

2'-FL and LNnT as novel foods in infant formula and other products

<p>Date received: 14/11/17 Date due for completion of administrative assessment: 5/12/17 Date completed: 7/12/17</p>		
<p>Applicant: Glycom A/S</p>		<p>Potentially affected standards: Schedule 25 (Permitted novel foods), Standard 2.9.1 (Infant formula products), Standard 2.9.3, Division 4 (FSFYC), Schedule 3 (Identity and purity)</p>
<p>Brief description of Application: To permit the voluntary use of 2'-O-Fucosyllactose (2'-FL) alone or in combination with Lacto-N-neotetraose (LNnT), produced by similar but independent proprietary fermentation processes, as novel foods in infant formula (IF), follow-on formula (FOF) and formulated supplementary foods for young children (FSFYC) (specifically milk products).</p>		
<p>Procedure: Major</p> <p>Reasons why: The application is seeking a variation to food regulatory measures that involves a very extensive and complex toxicological, nutritional and microbiological assessment. This will include development of a new approach to assess health benefit that will require public consultation. Also, targeted consultation with key stakeholders or special interest groups and establishment of an expert advisory group may also be required.</p>	<p>Estimated total hours: 2160 hrs</p> <p>Reasons why: The application is likely to involve extensive contributions from many disciplines within FSANZ to address the scientific and technical complexity.</p>	<p>Provisional estimated start work: When fees are received: Statutory deadline 10 January 2018</p>

Decision

Application accepted

Date: 7/12/17

Has the Applicant requested confidential commercial information status?

Yes No

What documents are affected?

Appendices V-a, V-b, VI-a, VI-b, VIII, IX, X

Has the Applicant provided justification for confidential commercial information request?

Yes No N/A

Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together?

Yes No

Details:

Novel food exclusivity

Charges

Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant?

Yes No

If yes, indicate the reason:

The Application seeks novel food exclusivity for the use of the Applicant's brand of 2'-FL alone or in combination with LNnT as novel foods. The available evidence is that the Applicant is the only party that produces 2'-FL and LNnT according to the specific technology and specifications described in the Application. The technology and specifications is proprietary to the Applicant and is not publically available. The substances produced by these proprietary processes can only be made available to third parties with the permission of Applicant. The Applicant will also clearly derive a financial gain from the measures sought by the Application, if approved.

The Application itself also states that an ECCB is likely to be conferred on the Applicant if the measures sought by the Application are approved.

Due date for fees: 10 January 2018 (received 9 January 2018)

Application Handbook requirements

Which Guidelines within the Part 3 of the *Application Handbook* apply to this Application?

3.1.1, 3.3.2, 3.5.2, 3.6.2, 3.6.3

Is the checklist completed?

Yes No

Does the Application meet the requirements of the relevant Guidelines?

Yes No

Does the Application relate to a matter that may be developed as a food regulatory measure, or that warrants a variation of a food regulatory measure?

Yes No

Is the Application so similar to a previous application or proposal for the development or variation of a food regulatory measure that it ought not to be accepted?

Yes No

Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?

Yes No

If yes, indicate which Procedure:

General – Level 2

Other Comments or Relevant Matters:

Three Ministerial Policy Guidelines are relevant to this application:

Regulation of infant formula products (for IF and FOF)

Intent of Part 2.9 – Special Purpose foods (for FSFYC)

Novel foods (for IF, FOF and FSFYC)

Consultation & assessment timeframe

Proposed length of public consultation periods:

1st call for submissions (6 weeks)

2nd call for submissions (6 weeks)

Targeted consultation is likely to be required with key stakeholders or special interest groups. The establishment of an expert advisory group is likely to be required to discuss and interpret scientific evidence and develop an assessment approach.

Proposed timeframe for assessment:

‘Early Bird Notification’ due: 7 December 2017

Commence assessment (clock start)	9 Jan 2018
Completion of assessment	early April 2018
Public comment	mid April – end May 2018
Preparation of draft food reg measure	end May – end July 2018
Public comment	early Aug – mid Sept 2018
Board to complete approval	early Dec 2018
Notification to Forum	mid Dec 2018
Anticipated gazettal if no review requested	late Feb 2019