

Administrative Assessment Report –Application A1251

2'-FL combined with galacto-oligosaccharides and inulin-type fructans in infant formula products.

1. Application details

<p>Date received: 04 February 2022 Date due for completion of administrative assessment: 28 February 2022 Date completed: 25 February 2022</p>		
<p>Applicant: Nutricia Australia Pty Ltd (Nutricia) & Chr. Hansen A/S</p>		<p>Potentially affected standard/s: Standard 2.9.1 - Infant formula products Schedule 29 - Special Purpose Foods</p>
<p>Brief description of Application: Seeking to permit 2'-FL in combination with galacto-oligosaccharides and inulin-type fructans in infant formula products.</p>		
<p>Procedure: General</p>	<p>Estimated total variable hours: 540 hours</p> <p>Reasons why: Anticipated low complexity (noting both ingredients are permitted and no changes to levels required). Safety and efficacy assessments on the use of the two ingredients in combination.</p>	<p>Estimated start date: Early April 2022</p>

2. Decision

<p>Application accepted</p> <p>Date: 25 February 2022</p> <p>If fees for ECCB are not received, date of rejection: 28 March 2022</p>

3. Additional matters

Has the Applicant requested information in the application is confidential commercial information (CCI) or confidential?

Yes (CCI)

What documents are affected?

Appendix A and one supporting reference

Has the Applicant provided redacted copies of documents containing CCI (i.e. CCI version and non CCI version and non CCI executive summary)?

No, claims for whole documents provided.

Has the Applicant provided justification for why information is CCI or confidential?

Yes

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

Yes

Details:

Exclusive use of the permission for 15 months after the date of gazettal.

4. Charges

The FSANZ Act provides that a charge must be imposed if the application confers an exclusive capturable commercial benefit (ECCB) on the Applicant.

Does FSANZ consider that the application confers an ECCB on the Applicant?

Yes

Reason:

The Applicant has requested exclusive use of the permission, if granted, for a period of 15 months after gazettal.

Due date for fees, or if paying by instalments the first instalment of the fees: 28 March 2022

5. Assessment against FSANZ Act 1991 requirements

Subsection 26(2)

(b) 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

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

No

(d) Are there any other matters relevant to the decision whether to accept or reject the application?

No

Does the application meet each of the following criteria required by subsection 22(2)?

(a) The application is in writing

Yes

(b) The application is in the form specified in guideline 3.1.1 of the Application Handbook

Yes

(c) The application includes all information and each thing that the section 23 guidelines of the Act state must be included in such an application.

Yes – General requirements (3.1.1), Substances used of a nutritive purpose (3.3.3), Special purpose foods – Infant formula products (3.6.2).

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

Yes

Indicate which Procedure:

General

Other Comments or Relevant Matters:

Nil

6. Consultation & assessment timeframe

Proposed length of public consultation periods:

6 weeks

Proposed timeframe for assessment

'Early Bird Notification' due: 04 April 2022

General Procedure:

Commence assessment (clock start)

Early April 2022

Public comment (6 weeks)

Late-June 2022

Board to complete approval

October 26 2022

Notification to Food Ministers' Meeting (FMM)

Early Nov 2022

Anticipated gazettal if no review requested

Early Jan 2023

