



22 July 2021
163-21

Administrative Assessment Report –Application A1234

Lactobacillus fermentum CECT5716 Lc40 as a Novel Food

1. Application details

Date received: 21 June 2021 Date due for completion of administrative assessment: 12 July 2021 Date completed:		
Applicant: BIOSEARCH, S.A.		Potentially affected standards: Standard 1.5.1 Schedule 3 Schedule 25
Brief description of Application: To permit the voluntary addition of the probiotic <i>Lactobacillus fermentum</i> CECT516 Lc40 to infant formula products, and fermented milk products (yoghurt).		
Procedure: General level 4	Estimated total variable hours: Maximum 680 hours Reasons why: First probiotic to be assessed for an application. Benefit assessment also required.	Estimated start date: 9 August 2021

2. Decision

Application accepted Date: 12 July 2021 If fees for ECCB are not received, date of rejection: Monday 9 August 2021

3. Additional matters

Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together? Yes Details: ECCB is conferred, and the applicant also requests exclusivity for the novel food.

4. Charges

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

Yes

Due date for fees: 9 August 2021

Does the Applicant want to expedite assessment (i.e. pay) for this Application?

No

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

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

Yes

If yes, indicate which Procedure:

General level – noting that level 4 is up to 680 hours, not 650 hours as mentioned in the application.

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: 16 August 2021

General level Procedure:

Commence assessment (clock start)	9 August 2021
Completion of assessment & preparation of draft food reg measure	Late Oct 2021
Public comment	Late Nov 2021 –or Mid Jan 2022
Board to complete approval	Late April 2022
Notification to Forum	Mid May 2022
Anticipated gazettal if no review requested	Late July 2022

