

## EXECUTIVE SUMMARY OF LACTOBACILLUS FERMENTUM CECT5716 – NOVEL FOOD APPLICATION

According to the FSANZ Record of Views formed in response to novel food inquiries, “new lactobacillus strains would be nontraditional foods in Australia and New Zealand”.

The probiotic *Lactobacillus fermentum* CECT5716 Lc40 has been used as an ingredient in Complementary Medicines in Australia and, although it has history of consumption in other countries (mainly in infant formula and food supplements), it has not been used as an ingredient in food applications in Australia, so it is defined as a non-traditional food. Thus, this strain is considered to be within the scope of the definition of novel food for the purposes of Standard 1.5.1 of the Australia New Zealand Food Standards Code.

*Lactobacillus fermentum* CECT5716 Lc40 is a probiotic obtained from human breast milk of healthy mothers and with the ability to be transferred to breast milk after oral intake.

Probiotics are live bacterial preparations or metabolites that promote the balance of microbial populations in the gut of humans and animals. *Lactobacillus fermentum* CECT5716 Lc40 is a Lactic Acid Bacteria (LAB). LAB refers to bacteria that can ferment carbohydrates and produce lactic acid as the main product. Lactic acid bacteria are a type of Gram-positive, non-spore-forming cocci or bacilli. Lactic acid bacteria have complex nutritional requirements, such as anaerobic, micro- or facultative anaerobic type; if they are classified according to their types, they can be divided into homo-fermentation which only produces lactic acid and hetero-fermentation which produces various products such as lactic acid, acetic acid, ethanol and carbon dioxide (Felis, G.E and Dellaglio, F., 2007).

*Lactobacillus fermentum* CECT5716 has not been genetically modified and has no plasmids. The total genome of *Lactobacillus fermentum* CECT5716 has been sequenced (Jimenez et al., 2010). The complete genome of *Lactobacillus fermentum* CECT5716 consists of a circular chromosome of 2,100,449 bp, with a GC content of 51.49%, and has no plasmids. The complete sequence is available in GenBank/EMBL under accession no. CP002033.

*Lactobacillus fermentum* CECT5716 is Gram positive, rod-shaped bacteria, smooth, white, with round colonies. It is facultative anaerob, heterofermentative, acid tolerant, catalase negative, oxidase negative, beta- glucuronidase activity negative, production of biogenic amines negative, mucin degradation negative (Martín et al., 2005). It is genetically stable (Appendix III). Antibiotic production is not known for *Lactobacillus* genus (Cárdenas et al., 2015). It does not harbor transmissible drug resistance genes encoding resistance to clinically used drugs (Cárdenas et al., 2015).

An important aspect of probiotic strains is their capabilities to colonize the human gut. *Lactobacillus fermentum* CECT5716 shows a high rate of adhesion to intestinal cells and is able to survive human gut transit (Martín et al., 2005). *Lactobacillus fermentum* CECT5716 also produces compounds that help to maintain the integrity of the human gut epithelium. This strain induces the production of mucins that may protect the intestinal epithelium from physical, chemical and bacteriological damage (Olivares et al., 2006). The consumption of *Lactobacillus fermentum* CECT5716 increases the production of short chain fatty

According to the Biosearch Management System, the documents must be reviewed after 3 years from the date of issue (if there are no prior significant changes)

acids (SCFAs) that constitute an important energy source for intestinal cells (Perán et al., 2006). *Lactobacillus fermentum* CECT5716 is endowed of an anti-infectious character since it produces antimicrobial substances, such as lactic acid, which inhibit the growth of pathogenic bacteria such as *E. coli*, *Salmonella* spp., *Listeria* spp., *Staphylococcus aureus*, etc, and inhibit pathogens' adhesion to the gut mucosa favoring the elimination of pathogens with the fecal bulk. The anti-infectious activity has been revealed by the capability of *Lactobacillus fermentum* CECT5716 to protect against gastrointestinal infections caused by *Salmonella choleraesuis* in an in vivo murine infection model (Olivares et al., 2006).

An application to vary the Code is required to approve the use of a new novel food or novel food ingredient. In this way, the purpose of this Application is to vary Standard 1.5.1 Novel Foods to include food ingredient *Lactobacillus fermentum* CECT5716 Lc40 as a Novel Food in this standard (specifically in Schedule 25-Permitted novel foods), to be used in infant formula and formulated supplementary food.

It is estimated that the approval of this strain as a novel food may require consideration and possible changes to the following Standards and their associated Schedules as applicable:

- Standard 2.9.1: Infant Formula Products: Infant formula and Follow-on formula.
- Standard 2.5.3-Fermented milk products: yogurt for general population and yogurt for young children (1-3 years).

The information presented in this application provides sufficient data and findings to demonstrate that the probiotic *Lactobacillus fermentum* CECT5716 Lc40, manufactured by BIOSEARCH, S.A. is safe to be used in infant formula and fermented milk products at the proposed dose.