

**APPLICATION FOR THE APPROVAL OF
2'-FUCOSYLLACTOSE (2'-FL) FROM *ESCHERICHIA COLI*
BL21(DE3) AS A SUBSTANCE USED FOR A NUTRITIVE
PURPOSE TO BE INCLUDED IN THE AUSTRALIA AND
NEW ZEALAND FOODSTANDARDS CODE**

EXECUTIVE SUMMARY

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EXECUTIVE SUMMARY

The applicant, Suzhou Yixi Biotech Co., Ltd. (Yixi) is submitting an application to Food Standards Australia New Zealand (FSANZ) concerning a purified human milk oligosaccharide (HMO) ingredient, 2'-fucosyllactose (2'-FL), produced via fermentation using *Escherichia coli* EC102 (genetically modified strain of *Escherichia coli* BL21(DE3)). In this application, the substance will be referred to as “Yixi’s 2'-FL” to distinguish it from other 2'-FL.

Yixi’s 2'-FL is structurally and chemically identical to 2'-FL naturally present in human breast milk as well as the 2'-FL ingredients currently permitted in *Australia New Zealand Food Standards Code* (the Code). Given that the microbial origin of Yixi’s 2'-FL can not match the source currently described in the Code, the purpose of this application is to amend *Schedules 3, Schedules 26, and Schedules 29*, so as to use Yixi’s 2'-FL in infant formula products as a nutritive substance.

Yixi is NOT request any change to the food categories and use levels of 2'-FL as permitted following FSANZ’s current assessments of 2'-FL. Consequently, the General Procedure, level 1 or 2, is considered the appropriate procedure to be adopted in assessing this application.

This application describes how the production stain is derived from the non-pathogenic bacterium *Escherichia coli* BL21, a host organism widely used to produce many oral and injectable human drugs. All genetic modifications are well described. Extensive purification steps remove viable cells and protein. Extensive qPCR testing demonstrated that no residual DNA from the genetically modified *E. coli* production strain was present in the final 2'-FL product.

There are no Codex assessments or standards that expressly name the use of 2'-FL as an ingredient in foods.

A GRAS notice of Yixi’s 2'-FL produced using recombinant *Escherichia coli* BL21(DE3) has been notified to the U.S. FDA and currently awaiting FDA’s response.

There are no costs to consumer, industry or governments from this application. Consumers may benefit from the availability of foods containing 2'-FL, a beneficial HMO, and food manufacturers may benefit from the opportunity to offer such products.

Yixi is requesting exclusive permission for its brand of 2'-FL, using the brand name “Synbilac”, to be added to infant formula products.