

Summary of the application: 2'-Fucosyllactose (2'-FL) from genetically modified *Corynebacterium glutamicum*

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The application is submitted for 2'-fucosyllactose (2'-FL) produced by microbial fermentation of a genetically modified strain of *Corynebacterium glutamicum*. 2'-FL is a trisaccharide consisting of L-fucose, D-galactose, and D-glucose, and currently authorised as a novel food ingredient under Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods for use in a variety of food products, including infant formula and follow-on formula and food supplements. The currently authorised 2'-FL ingredients are manufactured by chemical synthesis or produced by microbial fermentation of genetically modified strains of *Escherichia coli* K-12 or BL21. The primary difference in the specifications for 2'-FL from different microbial sources is limited to the carbohydrate components, specifically the levels of difucosyllactose, lactose, fucose, 3-fucosyllactose, fucosylgalactose, 2'-fucosyl-D-lactulose, glucose, and galactose. These differences are not considered to be a safety concern as they relate to innocuous and structurally related carbohydrate components.

Advanced Protein Technologies Corp. (APTech) is seeking to amend the specification of 2'-FL as available in the European Union (EU) Union list of novel foods to include another microbial source for 2'-FL. This application is not intended for a new ingredient and only information that is relevant to support the new microbial source is presented in the application.

2'-FL as manufactured by APTech has been demonstrated to be chemically and structurally identical to other 2'-FL ingredients currently on the EU marketplace and to 2'-FL naturally occurring in breast milk. Analytical data demonstrate that no significant changes in the composition or structure of APTech's 2'-FL has been made that would negatively impact its nutritional value, metabolism, or level of undesirable substances compared to 2'-FL ingredients that are currently approved.

APTech's 2'-FL is a highly pure ingredient ( $\geq 94\%$ ) that is absent of chemical or microbial contaminants. In the first step of manufacturing, the production strain undergoes fermentation to produce the 2'-FL, which is then isolated and purified in downstream processing steps. The 2'-FL ingredient is a purified white to off-white/ivory powder that is produced by a microbial process similar to other sources of 2'-FL outlined in the Union list (e.g., microbial fermentation of a genetically modified strain of *E. coli* K-12 or BL21). The specifications for 2'-FL produced by microbial fermentation of a genetically modified strain of *C. glutamicum* are similar to the specifications outlined in the Union list for 2'-FL produced by other microbial sources.

The 2'-FL from *C. glutamicum* is not genotoxic as assessed in a bacterial reverse mutation test, chromosome aberration test, and *in vivo* mammalian micronucleus test. In a 90-day toxicity study conducted in juvenile Sprague-Dawley rats, the no-observed-adverse-effect-level of 2'-FL from *C. glutamicum* was concluded to be 7,500 mg/kg/day, the highest dose tested. Residual protein levels were demonstrated to be absent in the final product, and the proteins encoded by the genes for 2'-FL biosynthesis were concluded to not pose an allergenic risk to consumers based on an *in silico* assessment. The safety of 2'-FL from *C. glutamicum* is further supported by toxicology and clinical studies on other 2'-FL ingredients previously reviewed by the EFSA NDA Panel.

The totality of evidence for 2'-FL from *C. glutamicum* supports its safety for the proposed food uses in existing food categories for 2'-FL as highlighted in Table 1 of the Union list.