

APPLICATION FOR THE EXTENSION OF USE FOR 2'-FUCOSYLLACTOSE/DIFUCOSYLLACTOSE NOVEL FOOD INGREDIENT FOR USE IN FOOD SUPPLEMENTS FOR INFANTS

***Regulation (EU) No 2015/2283 of the European
Parliament and of the Council of 25 November 2015
Concerning Novel Foods and Novel Food Ingredients***

SUMMARY

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Summary

2'-Fucosyllactose/difucosyllactose mixture is currently approved in the European Union (EU) within Commission Implementing Regulation (EU) 2019/1979 of 26 November 2019 authorising the placing on the market of 2'-fucosyllactose/difucosyllactose mixture as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470¹.

Within this application we seek to clarify the identity and specification for 2'-fucosyllactose/difucosyllactose mixture. Specifically, we propose to remove the method of drying (since the moisture content is already set within the specification and we did not specify the form of drying in our original application) and to simply include 3-fucosyllactose in the assay value for key oligosaccharides (naturally present in human breast milk) rather than with the "Sum of other carbohydrates".

Authorised Novel Food	Specification
2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)	<p>Description/Definition: 2'-Fucosyllactose/Difucosyllactose mixture is a purified, white to off-white amorphous powder or agglomerates that is produced by a microbial process. After purification, the 2'-Fucosyllactose/Difucosyllactose mixture is isolated by spray drying.</p> <p>Source: Genetically modified strain of <i>Escherichia coli</i> strain K-12 DH1</p> <p>Characteristics/Composition</p> <p>Appearance: White to off white powder or agglomerates</p> <p>Sum of 2'-Fucosyllactose, 3-fucosyllactose, Difucosyllactose, Lactose and Fucose (% of dry matter): ≥ 92,0 % (w/w)</p> <p>Sum of 2'-fucosyllactose and difucosyllactose (% of dry matter): ≥ 85,0 % (w/w)</p> <p>2'-Fucosyllactose (% of dry matter): ≥ 75,0 % (w/w)</p> <p>Difucosyllactose (% of dry matter): ≥ 5,0 % (w/w)</p> <p>D-Lactose: ≤ 10,0 % (w/w)</p> <p>L-Fucose: ≤ 1,0 % (w/w)</p> <p>2'-Fucosyl-D-lactulose: ≤ 2,0 % (w/w)</p> <p>Sum of other carbohydrates (*1): ≤ 6,0 % (w/w)</p> <p>Moisture: ≤ 6,0 % (w/w)</p> <p>Ash, sulfated: ≤ 0,8 % (w/w)</p> <p>pH (20 °C, 5 % solution): 4,0-6,0</p> <p>Residual protein: ≤ 0,01 % (w/w)</p> <p>Microbiological criteria:</p> <p>Aerobic mesophilic bacteria total plate count: ≤ 1000 CFU/g</p> <p><i>Enterobacteriaceae</i>: ≤ 10 CFU/g</p> <p><i>Salmonella</i> sp.: Negative/25 g</p>

¹ Commission implementing Regulation (EU) 2019/1979 of 26 November 2019 authorising the placing on the market of 2'-Fucosyllactose/Difucosyllactose mixture as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470. Available online at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1575968519252&uri=CELEX:32019R1979>

	Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units
(*1) 3-Fucosyllactose , 2-Fucosyl-galactose, Glucose, Galactose, Mannitol, Sorbitol, Galactitol, Trihexose, Allo-lactose and other structurally related carbohydrates	

Within Section 2.b.1 of the original application (also available on the Portal) we stated:

“the concentrated 2’-FL/DFL mixture is subsequently spray or freeze dried (STEP 10)”.

The batch data provided in the original dossier included freeze-dried material.

In this application we propose to update/correct the uses already approved in the EU within Commission Implementing Regulation (EU) 2019/197911. We believe this would simply be an administrative/corrigendum amendment to the Union List entry to clarify and harmonise with regard to the original application and EFSA opinion and how the use in “growing up milks” is more clearly presented for 2’-FL, Lacto-*N*-neotetraose (LNnT) and lacto-*N*-tetraose (LNT) within Commission Implementing Regulation (EU) 2017/2470 Union List (as amended). We would simply (in line with Table 4 of the EFSA Opinion) wish to add a row:

Specified Food Category	Maximum Use Levels
Milk-based drinks and similar products intended for young children	1.2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
	10 g/kg for products other than beverages

There is no change to any other aspect of the approval requested herein.