

APPLICATION FOR THE EXTENSION OF USE FOR 2'-FUCOSYLLACTOSE/DIFUCOSYLLACTOSE MIXTURE 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

SUBMITTED BY:



Glycom A/S
Kogle Allé 4
2970 Hørsholm
Denmark

Glycom A/S is a (sub-)division of DSM Nutritional Products Ltd, a company with registered address at Wurmisweg 576, 4303 Kaiseraugst, Switzerland

Application for the Extension of Use for 2'-Fucosyllactose/Difucosyllactose Mixture Novel Food Ingredient for Use in Food Supplements for Infants

2'-Fucosyllactose/difucosyllactose mixture (2'-FL/DFL) 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. 2'-Fucosyllactose/difucosyllactose mixture is approved in a wide variety of foods including infant and follow-on formula and food supplements as reproduced in Table 1, below.

Specified Food Category	Maximum Levels	Additional Specific Labelling Requirements
Infant formula as defined in Regulation (EU) No 609/2013	1.6 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	The designation of the novel food on the labelling of the foodstuffs containing it shall be "2'-fucosyllactose/difucosyllactose mixture".
Follow-on formula as defined in Regulation (EU) No 609/2013	1.2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	The labelling of food supplements containing the 2'-fucosyllactose/difucosyllactose mixture shall bear a statement that they should not be used if breast milk or other foods containing added 2'-fucosyllactose and/or difucosyllactose are consumed the same day.
Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	4.0 g/day	

Glycom A/S hereby applies to extend the currently permitted uses for food supplements (which currently exclude food supplements for infants) to specifically permit food supplements for that age group *via* amending the entry and risk management measures in the current Union List to those presented in Table 2 below.

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/?uri=CELEX%3A02017R2470-20210516>

FoodEx2 Name	Specific Proposed Food-Use	Maximum Proposed Use Level	Additional Specific Labelling Requirement
Food supplements and similar preparations	Food supplements in liquid and solid form for infants up to 6 months of age as defined in Directive 2002/46/EC to be added to food	1.6 g/day	Food supplements containing 2'-fucosyllactose/difucosyllactose shall bear a statement that the food supplement should not be given to infants, young children and children under 10 years of age where they consume breast milk or other foods with added 2'-fucosyllactose and/or difucosyllactose within the same twenty four hour period.
	Food supplements in liquid and solid form for infants over to 6 months of age as defined in Directive 2002/46/EC to be added to food	1.2 g/day	

The addition of 2'-FL/DFL to the proposed use in supplements, along with the intended labelling and use restrictions proposed would result in no significant increase to the intake of 2'-FL or DFL in infants.