

APPLICATION FOR THE EXTENSION OF USE FOR 2'-FUCOSYLLACTOSE 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:



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

2'-Fucosyllactose (2'-FL) is currently approved in the European Union (EU) within 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 (as amended)¹. 2'-FL 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	1.2 g/L alone or in combination with up to 0.6 g/L of lacto- <i>N</i> -neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be '2'-fucosyllactose'. 2. The labelling of food supplements containing 2'-fucosyllactose shall bear a statement that the supplements should not be used if other foods with added 2'-fucosyllactose are consumed the same day.
Follow-on formula as defined in Regulation (EU) No 609/2013	1.2 g/L alone or in combination with up to 0.6 g/L of lacto- <i>N</i> -neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	3. The labelling of food supplements containing 2'-fucosyllactose intended for young children shall bear a statement that the supplements should not be used if breast milk or other foods with added 2'-fucosyllactose are consumed the same day.
Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	30 g/day for general population 1.2 g/day for young children	

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 with those presented in Table 2 .

Food Categories, Conditions of Use and Labelling Requirements

FoodEx2 Name	Specific Proposed Food-Use	Maximum Proposed Use level	Additional Specific Labelling Requirement
A03SJ Food supplements and similar preparations	Food supplements as defined in Directive 2002/46/EC	1.2 g/day for infants	3. Food supplements containing 2'-fucosyllactose 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 within the same twenty-four-hour period.

¹ 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 (as amended). Most recent consolidated Union List available online at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R2470-20210516>

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