APPLICATION FOR THE EXTENSION OF USE FOR LACTO-*N*-NEOTETRAOSE 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 Lacto-*N*-neotetraose Novel Food Ingredient for Use in Food Supplements for Infants

Lacto-*N*-neotetraose is currently approved in the European Union 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]. LNnT is approved in a wide variety of foods including infant and follow-on formula and food supplements as reproduced in Table 1 below:

Table 1 Existing Approvals for LNnT Related to Infants

Specified Food Category	Maximum Levels	Additional Specific Labelling Requirements
Infant formula as defined in Regulation (EU) No 609/2013	0.6 g/L in combination with up to 1.2 g/L of 2'-fucosyllactose at a ratio of 1:2 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 "lacto-*N*-neotetraose"
Follow-on formula as defined in Regulation (EU) No 609/2013	0.6 g/L in combination with up to 1.2 g/L of 2'-fucosyllactose at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	2. The labelling of food supplements containing lacto-*N*-neotetraose shall bear a statement that the supplements should not be used if other foods with added lacto-*N*-neotetraose are consumed the same day.
Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	1.5 g/day for general population 0.6 g/day for young children	3. The labelling of food supplements containing lacto-*N*-neotetraose intended for young children shall bear a statement that the supplements should not be used if breast milk or other foods with added lacto-*N*-neotetraose are consumed the same 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 with those presented in Table 2 .

[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

Food Categories, Conditions of Use and Labelling Requirements

Table 2	**Proposed Amendment to the Approved Food Categories of LNnT**		
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	0.6 g/day in combination with up to 1.2 g/day of 2'-fucosyllactose at a ratio of 1:2 as consumed for infants	3. Food supplements containing lacto-*N*-neotetraose 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 lacto-*N*-neotetraose within the same twenty-four-hour period.

The addition of LNnT 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 LNnT in infants.