APPLICATION FOR THE EXTENSION OF USE FOR LACTO-*N*-TETRAOSE (LNT) 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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Glycom A/S is a (sub-)division of DSM Nutritional Products Ltd, a company with registered address at Wurmisweg 576, 4303 Kaiseraugst, Switzerland

Lacto-*N*-tetraose (LNT) 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]. LNT 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 LNT Related to Infants

Specified Food Category	Maximum Levels	Additional Specific Labelling Requirements
Infant formula as defined in Regulation (EU) No 609/2013	0.8 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 "lacto-*N*-tetraose". The labelling of food supplements containing the lacto-*N*-tetraose shall bear a statement that they should not be used if breast milk or other foods containing added lacto-*N*-tetraose is consumed the same day.
Follow-on formula as defined in Regulation (EU) No 609/2013	0.6 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	
Processed cereal-based food and baby food for infants and young children as defined under Regulation (EU) No 609/2013	0.6 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 5 g/kg for products other than beverages	
Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	2.0 g/day for young children, children, adolescents, and adults	

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] 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 LNT			
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	0.8 g/day	Food supplements containing lacto-*N*-tetraose 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*-tetraose within the same twenty-four-hour period.
	Food supplements in liquid and solid form for infants over 6 months of age as defined in Directive 2002/46/EC to be added to food	0.6 g/day	

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