

APPLICATION FOR AMENDMENT OF THE NOVEL FOOD INGREDIENT SPECIFICATION OF THE HUMAN-IDENTICAL MILK OLIGOSACCHARIDE LACTO-N-NEOTETRAOSE

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

Non-Confidential Summary of the Application

SUBMITTED BY:



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This dossier has been prepared in accordance with the requirements of Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods¹, supported by the European Food Safety Authority (EFSA) NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies) Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (EFSA NDA Panel, 2016) and EFSA's Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283 (EFSA, 2018).

¹ Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. OJ L 351, 30.12.2017, p. 64–71.

Application for Amendment of the Novel Food Ingredient Specification of the Human-Identical Milk Oligosaccharide Lacto-*N*-neotetraose

Summary

Glycom A/S (Kogle Allé 4, 2970 Hørsholm, Denmark) submits the present application in order to update the Union list on novel foods to amend the specification of lacto-*N*-neotetraose (LNnT) from the microbial *Escherichia coli* (*E. coli*) K-12 source as specified in Table 1 below. No other changes to the existing specification are proposed.

Table 1 Proposed Amendments to the Specifications for LNnT from Genetically Modified Strain of *E. coli* K-12 in the EU Union List of Novel Foods

Parameter	Proposed Amendments	Specification for LNnT (Microbial Source) in the EU Union List ^{a,b}
Description	Lacto- <i>N</i> -neotetraose (LNnT) is a white to off-white powder that is produced by a microbial process. Lacto-<i>N</i>-neotetraose is isolated by crystallisation.	Lacto- <i>N</i> -neotetraose is a white to off-white powder that is produced by a microbiological process. Lacto- <i>N</i> -neotetraose is isolated by crystallisation.
Purity		
Sum of specified saccharides (water-free)	≥92% (NEW)	Not specified
• LNnT (water-free)	≥80%	≥92%
• D-Lactose	≤10%	≤3.0%
• Lacto- <i>N</i> -triose II	No change	≤3.0%
• <i>para</i> -Lacto- <i>N</i> -neohexaose	≤5.0%	≤3.0%
• LNnT fructose isomer	No change	≤1.0%
Microbiological Criteria		
Aerobic mesophilic bacteria total count	≤3,000 CFU/g	≤500 CFU/g
Yeasts	≤100 CFU/g	≤10 CFU/g
Moulds	≤100 CFU/g	≤10 CFU/g

CFU = colony forming units; *E. coli* = *Escherichia coli*; EU = European Union; LNnT = lacto-*N*-neotetraose.

^a Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods. OJ L 187, 24.7.2018, p. 1–133.

^b The LNnT microbial source entry in the Union List is based on Glycom's notification of substantial equivalence of LNnT. There were no applications from other manufacturers.

Consistent with the omission of the crystallisation step from the production of 2'-fucosyllactose (2'-FL) from microbial sources (another human-identical milk oligosaccharide that is authorised as a novel food in the EU), Glycom has also optimised its manufacturing technology to allow to produce high-purity LNnT without the need for a crystallisation step.

This modification in the production process results in an increase in the levels of D-lactose and *para*-lacto-*N*-neohexaose (*para*-LNnH) and corresponding inversely-related lower levels of LNnT; D-lactose and *para*-LNnH are product-related carbohydrates that are already present in the currently authorised LNnT preparation. The proposed new parameter for the "Sum of specified saccharides" (i.e. LNnT, D-lactose, lacto-*N*-triose II, *para*-LNnH, and LNnT fructose isomer) ensures that the overall purity level does not decrease.

Additionally, an amendment of the microbiological criteria is proposed for aerobic mesophilic bacteria total count ($\leq 3,000$ CFU/g), yeasts count (≤ 100 CFU/g) and moulds count (≤ 100 CFU/g). These changes will harmonise the microbiological criteria for LNnT (microbial source) with the limits set forth for 2'-FL obtained from genetically modified *E. coli* K-12 in the EU Union List.

In this application, Glycom has provided data to show that:

1. The production process is not changed compared to the processes currently approved for LNnT, and there are no new processing aids.
2. There is no qualitative change in composition.
3. There is no significant change in nutritional properties and therefore metabolism.
4. There is no change to the profile of “undesirable substances”.