

APPLICATION FOR AMENDMENT OF THE NOVEL FOOD INGREDIENT SPECIFICATION OF THE HUMAN- IDENTICAL MILK OLIGOSACCHARIDE 2'-FUCOSYLLACTOSE

***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:



Glycom A/S
Kogle Allé 4
2970 Hørsholm
Denmark

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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 2'-Fucosyllactose

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 2'-fucosyllactose (2'-FL) 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 Specification for 2'-FL from Genetically Modified Strain of *E. coli* K-12 in the EU Union List of Novel Foods

Parameter	Proposed Amendments to the Specification for 2'-FL from GM Strain of <i>E. coli</i> K-12	Specification for 2'-FL (Microbial Source) in the EU Union List ^a	
		Derived from <i>E. coli</i> K-12 (Glycom, Dupont, FrieslandCampina)	Derived from <i>E. coli</i> BL21 (Jennewein)
Purity			
Sum of specified saccharides	≥90% (NEW)	Not specified	Not specified
• 2'-Fucosyllactose	≥83%	≥90%	≥90%
• D-Lactose	≤10%	≤3.0%	≤5.0%
• L-Fucose	≤2.0%	≤2.0%	≤3.0%
• Difucosyl-D-lactose	≤5.0%	≤2.0%	≤5.0%
• 2'-Fucosyl-D-lactulose:	≤1.0%	≤1.0%	Not specified

2'FL = 2'-fucosyllactose; *E. coli* = *Escherichia coli*; EU = European Union ; GM = genetically modified.

Put simply, the difucosyllactose (DFL) content is aligned with the existing maximum set for *E. coli* BL21 microbial source, and the lactose level is slightly increased. This results in a slightly lower level of 2'-FL but the proposed new "Sum of specified saccharides" (2'-fucosyllactose, D-lactose, L-fucose, difucosyl-D-lactose, 2'-fucosyl-D-lactulose) parameter ensures the overall purity level does not decrease.

Glycom has provided data to show that:

1. The production process is not changed compared to the processes currently approved for 2'-FL, 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".