*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

**COMMISSION IMPLEMENTING REGULATION (EU) …/...**

**of XXX**

**authorising the placing on the market of 2’-fucosyllactose/difucosyllactose mixture as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001[[1]](#footnote-1), and in particular Article 12 thereof,

Whereas:

1. Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
2. Pursuant to Article 8 of Regulation (EU) 2015/2283 Commission Implementing Regulation (EU) 2017/2470[[2]](#footnote-2) was adopted, which establishes a Union list of authorised novel foods.
3. Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on updating the Union list.
4. On 30 April 2018, the company Glycom A/S. (‘the Applicant’) made a request to the Commission within the meaning of Article 10(1) of Regulation (EU) 2015/2283 to place a mixture of 2’-fucosyllactose/difucosyllactose (‘2’-FL/DFL’) obtained by microbial fermentation with a genetically modified strain of *Escherichia coli* K12, on the Union market as a novel food. The application requests for the 2’-fucosyllactose/difucosyllactose mixtureto be used in dairy products and analogues, bakery wares, beverages, and foods for infants and young children, foods for special medical purposes, foods for weight control as defined in Regulation (EU) No 609/2013of the European Parliament and of the Council[[3]](#footnote-3) and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[[4]](#footnote-4).
5. The Applicant also made a request to the Commission for protection of proprietary data for a number of studies submitted in support of the application, namely, the proprietary analytical reports via nuclear magnetic resonance (‘NMR’) on the structure comparison of 2’-fucosyllactose and difucosyllactose produced by bacterial fermentation with 2’-fucosyllactose and difucosyllactose naturally present in human milk[[5]](#footnote-5), the detailed characterisation data on the production bacterial strains and their certificates[[6]](#footnote-6),[[7]](#footnote-7), the specifications for the raw materials and processing aids[[8]](#footnote-8), the certificates of analyses of the various 2’-FL/DFL batches[[9]](#footnote-9), the analytical methods and validation reports[[10]](#footnote-10), the 2’-FL/DFL stability reports[[11]](#footnote-11), the laboratory accreditation certificates[[12]](#footnote-12), the 2’-FL/DFL intake assessment reports[[13]](#footnote-13), the summary table of the statistically significant observations in the toxicity studies[[14]](#footnote-14), a bacterial reverse mutation test with 2’-FL/DFL[[15]](#footnote-15), an *in vitro* mammalian cell micronucleus test with 2’-FL/DFL[[16]](#footnote-16), a 14-day oral toxicity study in the neonatal rat with 2’-FL/DFL[[17]](#footnote-17), a 90-day oral toxicity study in the neonatal rat with 2’-FL/DFL[[18]](#footnote-18), a bacterial reverse mutation test with 2’-FL[[19]](#footnote-19) two *in vitro* mammalian cell micronucleus tests with 2’-FL[[20]](#footnote-20),[[21]](#footnote-21), and a 90-day oral toxicity study in the neonatal rat with 2’-FL[[22]](#footnote-22).
6. On 29 June 2018, the Commission consulted the Authority asking it to carry out an assessment of 2’-FL/DFL as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283*.*
7. On 15 May 2019, the Authority adopted its "Scientific Opinion on the safety of 2’-fucosyllactose/difucosyllactose mixture as a novel food pursuant to Regulation (EU) 2015/2283"[[23]](#footnote-23). That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
8. That opinion gives sufficient grounds to establish that the 2’-fucosyllactose/difucosyllactose mixture, in the proposed uses and use levels when used in infant and follow-on formulae, in total diet replacement foods for weight control, in foods for special medical purposes, and in food supplements, complies with Article 12(1) of Regulation (EU) 2015/2283.
9. In its opinion on the 2’-fucosyllactose/difucosyllactose mixture, the Authority considered that the data from the analytical NMR reports on the structure comparison of 2’-fucosyllactose and difucosyllactose produced by bacterial fermentation with the 2’-fucosyllactose and the difucosyllactose naturally present in human milk, the detailed characterisation data on the production bacterial strains, the specifications for the raw materials and processing aids, the certificates of analyses of the various 2’-FL/DFL batches, the bacterial reverse mutation test with 2’-FL/DFL, the *in vitro* mammalian cell micronucleus test with 2’-FL/DFL, the 90-day oral toxicity study in the neonatal rat with 2’-FL/DFL, and the summary table of the statistically significant observations in the toxicity studies served as a basis to establish the safety of the novel food. Therefore, it is considered that the conclusions on the safety of the 2’-fucosyllactose/difucosyllactose mixture could not have been reached without the data from the report of this study.
10. Following the receipt of the Authority's opinion, the Commission requested the Applicant to further clarify the justification provided with regard to their proprietary analytical NMR reports on the structure comparison of 2’-fucosyllactose and difucosyllactose produced by bacterial fermentation with the 2’-fucosyllactose and the difucosyllactose present in human milk, the detailed characterisation data on the production bacterial strains, the specifications for the raw materials and processing aids, the certificates of analyses of the various 2’-FL/DFL batches, the bacterial reverse mutation test with 2’-FL/DFL, the *in vitro* mammalian cell micronucleus test with 2’-FL/DFL, the 90-day oral toxicity study in the neonatal rat with 2’-FL/DFL, and the summary table of the statistically significant observations in the toxicity studies, and to clarify their claim to an exclusive right of reference to these reports and studies, as referred to in points (a) and (b) of Article 26 of Regulation (EU) 2015/2283.
11. The Applicant also declared that, at the time the application was submitted, they held proprietary and exclusive rights of reference to the study under national law and that therefore third parties could not lawfully access or use this study. The Commission assessed all the information provided by the applicant and considered that the Applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283.
12. Accordingly, as provided for under Article 26(2) of Regulation (EU) 2015/2283, the NMR analytical reports on the structure comparison of 2’-fucosyllactose and difucosyllactose produced by bacterial fermentation with the 2’-fucosyllactose and the difucosyllactose naturally present in human milk, the detailed characterisation data on the production bacterial strains, the specifications for the raw materials and processing aids, the certificates of analyses of the various 2’-FL/DFL batches, the bacterial reverse mutation test with 2’-FL/DFL, the *in vitro* mammalian cell micronucleus test with 2’-FL/DFL, the 90-day oral toxicity study in the neonatal rat with 2’-FL/DFL, and the summary table of the statistically significant observations in the toxicity studies contained in the Applicant's file, and without which the novel food could not have been assessed by the Authority, should not be used by the Authority for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. As a consequence, the placing on the market within the Union of the novel food authorised by this Regulation should be restricted to the Applicant for a period of five years.
13. However, restricting the authorisation of this novel food and of the reference to the analytical NMR reports on the structure comparison of 2’-fucosyllactose and difucosyllactose produced by bacterial fermentation with the 2’-fucosyllactose and the difucosyllactose naturally present in human milk, the detailed characterisation data on the production bacterial strains, the specifications for the raw materials and processing aids, the certificates of analyses of the various 2’-FL/DFL batches, the bacterial reverse mutation test with 2’-FL/DFL, the *in vitro* mammalian cell micronucleus test with 2’-FL/DFL, the 90-day oral toxicity study in the neonatal rat with 2’-FL/DFL, and the summary table of the statistically significant observations in the toxicity studies contained in the Applicant's file, for the sole use of the Applicant, does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting the authorisation under this Regulation.
14. Regulation (EU) No 609/2013 of the European Parliament and of the Council[[24]](#footnote-24) lays down requirements on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. The use of the 2’fucosyllactose and difucosyllactose mixture should be authorised without prejudice to that Regulation.
15. Directive 2002/46/EC lays down requirements on food supplements. The use of the 2’fucosyllactose and difucosyllactose mixture should be authorised without prejudice to that Directive.
16. The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

1. The 2’-fucosyllactose/difucosyllactose mixture as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2. For a period of five years from the date of entry into force of this Regulation only the applicant:

* Company: Glycom A/S.
* Address: Kogle Allé 4, DK-2970 Hørsholm, Denmark;

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 to this Regulation or with the agreement of Glycom A/S.

3. The entry in the Union list referred to in the first paragraph shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

4. The authorisation provided for in this Article shall be without prejudice to the provisions of Regulation (EU) No 609/2013 and to the provisions of Directive 2002/46/EC.

*Article 2*

Studies and reports contained in the application file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the Applicant as fulfilling the requirements laid down in Article 26(2) of Regulation 2015/2283, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Glycom A/S.

*Article 3*

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

*Article 4*

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European* Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*

*The President*

*Jean-Claude JUNCKER*

1. OJ L 327, 11.12.2015, p. 1. [↑](#footnote-ref-1)
2. 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, (OJ L 351, 30.12.2017, p. 72). [↑](#footnote-ref-2)
3. Regulation of the European Parliament and of the Council (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p.35). [↑](#footnote-ref-3)
4. Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p.51). [↑](#footnote-ref-4)
5. Glycos 2018 (unpublished) [↑](#footnote-ref-5)
6. Glycom 2018 (unpublished) [↑](#footnote-ref-6)
7. Glycom/DSMZ 2018 (unpublished) [↑](#footnote-ref-7)
8. Glycom 2018 (unpublished) [↑](#footnote-ref-8)
9. Glycom 2018 (unpublished) [↑](#footnote-ref-9)
10. Glycom 2018 (unpublished) [↑](#footnote-ref-10)
11. Glycom 2018 (unpublished) [↑](#footnote-ref-11)
12. Glycom 2018 (unpublished) [↑](#footnote-ref-12)
13. Glycom 2018 (unpublished) [↑](#footnote-ref-13)
14. Flaxmer 2018 (unpublished) and Philips K. R., N. Baldwin, B. Lynch, J. Flaxmer, A. Šoltésová, M. H. Miks, C. H. Röhrig. 2018. Safety evaluation of the human-identical milk oligosaccharides 2’-fucosyllactose and difucosyllactose. Food and Chemical Toxicology 120:552-565. [↑](#footnote-ref-14)
15. Šoltésová, 2017 (unpublished) and Philips et al. 2018. Food and Chemical Toxicology 120:552-565. [↑](#footnote-ref-15)
16. Gilby 2017 (unpublished) and Philips et al. 2018. Food and Chemical Toxicology 120:552-565. [↑](#footnote-ref-16)
17. Flaxmer 2017 (unpublished) and Philips et al. 2018. Food and Chemical Toxicology 120:552-565. [↑](#footnote-ref-17)
18. Flaxmer 2018 (unpublished) and Philips et al. 2018. Food and Chemical Toxicology 120:552-565. [↑](#footnote-ref-18)
19. Verspeek-Rip 2015 (unpublished) [↑](#footnote-ref-19)
20. Verbaan 2015a (unpublished) [↑](#footnote-ref-20)
21. Verbaan 2015b (unpublished) [↑](#footnote-ref-21)
22. Penard 2015 (unpublished) [↑](#footnote-ref-22)
23. EFSA Journal 2019;17(6):5717 [↑](#footnote-ref-23)
24. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009, (OJ L 181, 29.6.2013, p. 35). [↑](#footnote-ref-24)