

COMMISSION IMPLEMENTING DECISION (EU) 2016/376**of 11 March 2016****authorising the placing on the market of 2'-O-fucosyllactose as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council***(notified under document C(2016) 1423)***(Only the Danish text is authentic)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ⁽¹⁾, and in particular Article 7 thereof,

Whereas:

- (1) On 23 June 2014, the company Glycom A/S made a request to the competent authorities of Ireland to place 2'-O-fucosyllactose on the market as a novel food ingredient.
- (2) On 3 October 2014, the competent food assessment body of Ireland issued its initial assessment report. In that report, it came to the conclusion that 2'-O-fucosyllactose meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.
- (3) On 9 October 2014, the Commission forwarded the initial assessment report to the other Member States.
- (4) Reasoned objections were raised within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97.
- (5) On 22 December 2014, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an assessment for 2'-O-fucosyllactose as a novel food ingredient in accordance with Regulation (EC) No 258/97.
- (6) On 29 June 2015, EFSA in its 'Scientific Opinion on the safety of 2'-O-fucosyllactose as a novel food ingredient pursuant to Regulation (EC) No 258/97' ⁽²⁾, concluded that 2'-O-fucosyllactose is safe for the proposed uses and use levels.
- (7) On 5 October 2015, the applicant sent a letter to the Commission and provided additional information to support the use and approval of 2'-O-fucosyllactose and lacto-N-neotetraose in food supplements for general population (excluding infants) under Regulation (EC) No 258/97.
- (8) On 14 October 2015, the Commission consulted EFSA asking it to carry out an assessment of the safety of these novel foods in food supplements also for children (excluding infants).
- (9) On 28 October 2015, EFSA in its 'Statement on the safety of lacto-N-neotetraose and 2'-O-fucosyllactose as novel food ingredients in food supplements for children' ⁽³⁾, concluded that 2'-O-fucosyllactose is safe for the proposed uses and use levels.
- (10) Commission Directive 96/8/EC ⁽⁴⁾ lays down requirements on foods intended for use in energy-restricted diets for weight reduction. Commission Directive 1999/21/EC ⁽⁵⁾ lays down requirements for dietary foods for special

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.⁽²⁾ EFSA Journal 2015; 13(7):4184.⁽³⁾ EFSA Journal 2015; 13(11):4299.⁽⁴⁾ Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22).⁽⁵⁾ Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29).

medical purposes. Directive 2002/46/EC of the European Parliament and of the Council ⁽¹⁾ lays down requirements on food supplements. Commission Directive 2006/125/EC ⁽²⁾ lays down requirements for processed cereal-based foods and baby foods for infants and young children. Commission Directive 2006/141/EC ⁽³⁾ lays down requirements for infant formulae and follow-on formulae. Regulation (EC) No 1925/2006 of the European Parliament and of the Council ⁽⁴⁾ lays down requirements on the addition of vitamins and minerals and of certain other substances to foods. Commission Regulation (EC) No 41/2009 ⁽⁵⁾ lays down requirements for the composition and labelling of foodstuffs suitable for people intolerant to gluten. Commission Implementing Regulation (EU) No 828/2014 ⁽⁶⁾ lays down the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food. The use of 2'-O-fucosyllactose should be authorised without prejudice to the requirements of those legislations

- (11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

2'-O-Fucosyllactose as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses defined and at the maximum levels established in Annex II without prejudice to the specific provisions of Directives 96/8/EC, 1999/21/EC, 2002/46/EC, 2006/125/EC, 2006/141/EC and Regulations (EC) No 1925/2006, (EC) No 41/2009 and Implementing Regulation (EU) No 828/2014

Article 2

1. The designation of 2'-O-fucosyllactose authorised by this Decision on the labelling of the foodstuffs containing it shall be '2'-O-fucosyllactose'.
2. Information shall be given to the consumer that food supplements containing 2'-O-fucosyllactose should not be used if other foods with added 2'-O-fucosyllactose are consumed the same day.
3. Information shall be given to the consumer that food supplements containing 2'-O-fucosyllactose intended for young children should not be used if breast milk or other foods with added 2'-O-fucosyllactose are consumed the same day.

Article 3

This Decision is addressed to Glycom A/S, Diplomvej 373, 2800 Kgs. Lyngby, Denmark.

Done at Brussels, 11 March 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

⁽¹⁾ 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).

⁽²⁾ Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p. 16).

⁽³⁾ Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ L 401, 30.12.2006, p. 1).

⁽⁴⁾ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

⁽⁵⁾ Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten (OJ L 16, 21.1.2009, p. 3).

⁽⁶⁾ Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (OJ L 228, 31.7.2014, p. 5).

ANNEX I

SPECIFICATION OF 2'-O-FUCOSYLLACTOSE

Definition:

Chemical name	α -l-Fucopyranosyl-(1 $\rightarrow$ 2)- β -d-galactopyranosyl-(1 $\rightarrow$ 4)-d-glucopyranose
Chemical formula	C ₁₈ H ₃₂ O ₁₅
Molecular weight	488,44 g/mol
CAS No	41263-94-9

Description: 2'-O-fucosyllactose is a white to off-white powder.

Purity:

Test	Specification
Assay	Not less than 95 %
D-Lactose	Not more than 1,0 w/w %
L-Fucose	Not more than 1,0 w/w %
Difucosyl-d-lactose isomers	Not more than 1,0 w/w %
2'-Fucosyl-d-lactulose	Not more than 0,6 w/w %
pH (20 °C, 5 % solution)	3,2-7,0
Water (%)	Not more than 9,0 %
Ash, sulphated	Not more than 0,2 %
Acetic acid	Not more than 0,3 %
Residual solvents (methanol, 2-propanol, methyl acetate, acetone)	Not more than 50 mg/kg singly Not more than 200 mg/kg in combination
Residual proteins	Not more than 0,01 %
Palladium	Not more than 0,1 mg/kg
Nickel	Not more than 3,0 mg/kg

Microbiological criteria:

Aerobic mesophilic bacteria total count	Not more than 500 CFU/g
Yeasts	Not more than 10 CFU/g
Moulds	Not more than 10 CFU/g
Residual endotoxins	Not more than 10 EU/mg

ANNEX II

AUTHORISED USES OF 2'-O-FUCOSYLLACTOSE

Food category	Maximum levels
Unflavoured pasteurised and sterilised (including UHT) milk-based products	1,2 g/l
Unflavoured fermented milk-based products	1,2 g/l beverages 19,2 g/kg products other than beverages
Flavoured fermented milk-based products including heat-treated products	1,2 g/l beverages 19,2 g/kg products other than beverages
Dairy analogues, including beverage whiteners	1,2 g/l beverages 12 g/kg for products other than beverages 400 g/kg for whitener
Cereal bars	12 g/kg
Table-top sweeteners	200 g/kg
Infant formulae as defined in Directive 2006/141/EC	1,2 g/l in combination with 0,6 g/l of lacto-N-neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Follow-on formulae as defined in Directive 2006/141/EC	1,2 g/l in combination with 0,6 g/l of lacto-N-neotetraose at a ratio of 2:1 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 in Directive 2006/125/EC	12 g/kg for products other than beverages 1,2 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer
Milk-based drinks and similar products intended for young children	1,2 g/l for milk-based drinks and similar products added alone or in combination with lacto-N-neotetraose, at concentrations 0,6 g/l, at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Dietary foods for special medical purposes as defined in Directive 1999/21/EC	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Foods intended for use in energy-restricted diets for weight reduction as defined in Directive 96/8/EC (only for products presented as a replacement for the whole of the daily diet)	4,8 g/l for drinks 40 g/kg for bars
Bread and pasta products for people intolerant to gluten as defined in Regulation (EC) No 41/2009 ⁽¹⁾	60 g/kg
Flavoured drinks	1,2 g/l

Food category	Maximum levels
Coffee, tea (excluding black tea), herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	9,6 g/l ⁽²⁾
Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	3,0 g/day for general population 1,2 g/day for young children

⁽¹⁾ From 20 July 2016 the category 'Bread and pasta products for people intolerant to gluten as defined in Regulation (EC) No 41/2009' shall be replaced by the following: 'Bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014'.

⁽²⁾ The maximum level refers to the products ready to use.