COMMISSION IMPLEMENTING DECISION (EU) 2016/375

of 11 March 2016

authorising the placing on the market of lacto-*N*-neotetraose as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2016) 1419)

(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 15 January 2014, the company Glycom A/S made a request to the competent authorities of Ireland to place lacto-*N*-neotetraose on the market as a novel food ingredient.

(2) On 10 June 2014, the competent food assessment body of Ireland issued its initial assessment report. In that report, it came to the conclusion that lacto-*N*-neotetraose meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.

(3) On 7 July 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 13 October 2014, the Commission consulted the European Food Safety Authority (EFSA), asking it to carry out an assessment for lacto-*N*-neotetraose 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 lacto-*N*-neotetraose as a novel food ingredient pursuant to Regulation (EC) No 258/97' ([2]), concluded that lacto-*N*-neotetraose 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 lacto-*N*-neotetraose 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):4183.
([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 lacto-*N*-neotetraose 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

Lacto-*N*-neotetraose 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 lacto-*N*-neotetraose authorised by this Decision on the labelling of the foodstuffs containing it shall be 'lacto-*N*-neotetraose'.

2. Information shall be given to the consumer that food supplements containing lacto-*N*-neotetraose should not be used if other foods with added lacto-*N*-neotetraose are consumed the same day.

3. Information shall be given to the consumer that food supplements containing lacto-*N*-neotetraose intended for young children should not be used if breast milk or other foods with added lacto-*N*-neotetraose 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

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[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 LACTO-*N*-NEOTETRAOSE

Definition:

Chemical name	β-d-Galactopyranosyl-(1→4)-2-acetamido-2-deoxy-β-d-glucopyranosyl-(1→3)-β-d-galactopyranosyl-(1→4)-d-glucopyranose
Chemical formula	$C_{26}H_{45}NO_{21}$
Molecular weight	707,63 g/mol
CAS No	13007-32-4

Description: Lacto-*N*-neotetraose is a white to off-white powder.

Purity:

Test	Specification
Assay	Not less than 96 %
D-Lactose	Not more than 1,0 w/w %
Lacto-N-triose II	Not more than 0,3 w/w %
Lacto-N-neotetraose fructose isomer	Not more than 0,6 w/w %
pH (20 °C, 5 % solution)	5,0-7,0
Water (%)	Not more than 9,0 %
Ash, sulphated	Not more than 0,4 %
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 LACTO-N-NEOTETRAOSE

Food category	Maximum levels
Unflavoured pasteurised and sterilised (including UHT) milk-based products	0,6 g/l
Unflavoured fermented milk-based products	0,6 g/l for beverages 9,6 g/kg for products other than beverages
Flavoured fermented milk-based products including heat-treated products	0,6 g/l for beverages 9,6 g/kg for products other than beverages
Dairy analogues, including beverage whiteners	0,6 g/l for beverages 6 g/kg for products other than beverages 200 g/kg for whitener
Cereal bars	6 g/kg
Table-top sweeteners	100 g/kg
Infant formulae as defined in Directive 2006/141/EC	0,6 g/l in combination with 1,2 g/l of 2′-*O*-fucosyllactose at a ratio of 1:2 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	0,6 g/l in combination with 1,2 g/l of 2′-*O*-fucosyllactose at a ratio of 1:2 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	6 g/kg for products other than beverages 0,6 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	0,6 g/l for milk-based drinks and similar products added alone or in combination with 2′-*O*-fucosyllactose, at concentrations 1,2 g/l, at a ratio of 1:2 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)	2,4 g/l for drinks 20 g/kg for bars
Bread and pasta products for people intolerant to gluten as defined in Regulation (EC) No 41/2009 [1]	30 g/kg
Flavoured drinks	0,6 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	4,8 g/l [2]
Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	1,5 g/day for general population 0,6 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.