DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2017/2201

of 27 November 2017

authorising the placing on the market of 2′-fucosyllactose produced with *Escherichia coli* strain BL21 as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2017) 7662)

(Only the German 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 4 August 2014, the company Jennewein Biotechnologie GmbH made a request to the competent authority of the Netherlands to place powder and liquid concentrate of the oligosaccharide 2′-fucosyllactose produced with a genetically modified strain of *Escherichia coli* BL21 on the Union market as novel food ingredient within the meaning of point (d) of Article 1(2) of Regulation (EC) No 258/97. The target population is the infant population.

(2) 2′-fucosyllactose falls outside the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council ([2]) as the genetically modified strain of *Escherichia coli* BL21 is used as a processing aid and the material derived from the genetically modified microorganism is not present in the novel food.

(3) On 3 June 2016, the competent authority of the Netherlands issued its initial assessment report. In that report it came to the conclusion that powder and liquid concentrate of the oligosaccharide 2′-fucosyllactose produced with a genetically modified strain of *Escherichia coli* BL21 meets the criteria for novel food ingredients set out in Article 3(1) of Regulation (EC) No 258/97.

(4) On 13 June 2016, the Commission forwarded the initial assessment report to the other Member States.

(5) 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. In particular, objections concerning elevated intake levels of 2′-fucosyllactose were raised. In accordance with Article 7(1) of Regulation (EC) No 258/97, a decision should be adopted taking into account the objections raised. The applicant consequently modified the request concerning the maximum amount of 2′-fucosyllactose in infant formulae and follow- on formulae. That change and additional explanations provided by the applicant alleviated the concerns to the satisfaction of Member States and of the Commission.

(6) Regulation (EU) No 609/2013 of the European Parliament and of the Council ([3]) lays down requirements for food intended for infants and young children. The use of 2′-fucosyllactose powder and liquid concentrate should be authorised without prejudice to that Regulation and to any other legislation that applies in parallel to Regulation (EC) No 258/97.

([1]) OJ L 43, 14.2.1997, p. 1.
([2]) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).
([3]) 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).

(7) 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

Without prejudice to Regulation (EU) No 609/2013, 2′-fucosyllactose powder and liquid concentrate as specified in Annex I to this Decision may be placed on the Union market as a novel food ingredient for the uses defined and at the maximum level established in Annex II to this Decision.

Article 2

The designation of 2′-fucosyllactose powder and liquid concentrate authorised by this Decision on the labelling of the foodstuffs shall be '2′-fucosyllactose' for the powder and for the liquid concentrate.

Article 3

This Decision is addressed to Jennewein Biotechnologie GmbH, Maarweg 32, 53619 Rheinbreitbach, Germany.

Done at Brussels, 27 November 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX I

SPECIFICATIONS OF 2′-FUCOSYLLACTOSE

Definition:

Chemical name	α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranoside
Chemical formula	$C_{18}H_{32}O_{15}$
Molecular mass	488,44 Da
CAS No.	41263-94-9

Description: 2′-fucosyllactose powder produced with a genetically modified strain of *Escherichia coli* BL21 is a white to ivory powder that is derived from 2′-fucosyllactose liquid concentrate by spray drying. The 2′-fucosyllactose liquid concentrate is a colourless to slight yellow clear 45 % w/v ± 5 % w/v aqueous solution.

Specifications of 2′-fucosyllactose powder

Specification Parameter		Limits
Physical parameter	White to ivory colour	
Chemical analysis	2′-fucosyllactose	≥ 90 %
	Lactose	≤ 5 %
	3-fucosyllactose	≤ 5 %
	Difucosyllactose	≤ 5 %
	Fucosylgalactose	≤ 3 %
	Glucose	≤ 3 %
	Galactose	≤ 3 %
	Fucose	≤ 3 %
GMO detection	Negative	
Water content		≤ 9,0 %
Protein content		≤ 100 µg/g
Total Ash		≤ 0,5 %
Contaminants	Lead	≤ 0,02 mg/kg
	Arsenic	≤ 0,2 mg/kg
	Cadmium	≤ 0,1 mg/kg
	Mercury	≤ 0,5 mg/kg
	Aflatoxin M_1	≤ 0,025 µg/kg
Microbial Parameters	Total Plate Count (TPC)	≤ 10^4 CFU/g
	Enterobacteria/Coliforms	absent in 11 g
	Yeast and Mould	≤ 100 CFU/g
	Salmonella spp.	Negative/100 g
	Cronobacter spp.	Negative/100 g
	Endotoxins	≤ 100 EU/g

CFU: Colony Forming Units; EU: Endotoxin Units

Specifications of 2′-fucosyllactose liquid concentrate

Specification Parameter		Limits
Physical parameter	Colourless to slightly yellow, clear solution	
Solids content		45 % w/v (+/– 5 % w/v) dry matter in water
Chemical analysis	2′-fucosyllactose	≥ 90 %
	Lactose	≤ 5 %
	3-fucosyllactose	≤ 5 %
	Difucosyllactose	≤ 5 %
	Fucosylgalactose	≤ 3 %
	Glucose	≤ 3 %
	Galactose	≤ 3 %
	Fucose	≤ 3 %
GMO detection	Negative	
Protein content		≤ 100 µg/g
Total Ash		≤ 0,5 %
Contaminants	Lead	≤ 0,02 mg/kg
	Arsenic	≤ 0,2 mg/kg
	Cadmium	≤ 0,1 mg/kg
	Mercury	≤ 0,5 mg/kg
	Aflatoxin M_1	≤ 0,025 µg/kg
Microbial Parameters	Total Plate Count (TPC)	≤ 5 000 CFU/g
	Enterobacteria/Coliforms	absent in 11 g
	Yeast and Mould	≤ 50 CFU/g
	Salmonella spp.	Negative/200 ml
	Cronobacter spp.	Negative/200 ml
	Endotoxins	≤ 100 EU/ml

CFU: Colony Forming Units; EU: Endotoxin Units

ANNEX II

Authorised uses of 2′-fucosyllactose powder and liquid concentrate

Food category	Maximum level
Infant formulae and follow-on formulae	1,2 gram 2′-fucosyllactose per litre final product ready for use marketed as such or reconstituted as instructed by the manufacturer.