COMMISSION IMPLEMENTING REGULATION (EU) 2021/2029

of 19 November 2021

authorising the placing on the market of 3-Fucosyllactose (3-FL) 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 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ([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]) establishing a Union list of authorised novel foods, was adopted.

(3) On 1 October 2019, the company DuPont Nutrition & Biosciences ApS ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place 3-Fucosyllactose (3-FL), obtained by microbial fermentation with a genetically modified strain of *Escherichia coli,* strain K12 MG1655, on the Union market as a novel food. The applicant requested for 3-FL to be used as a novel food in unflavoured pasteurised and unflavoured sterilised (including Ultra High Temperature, 'UHT') milk products, flavoured and unflavoured fermented milk based products including heat-treated products, cereal bars, dairy analogues and non-dairy yoghurts, beverages (flavoured drinks, energy drinks, sports drinks), infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([3]), processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013, total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013, foods for special medical purposes as defined in Regulation (EU) No 609/2013, milk based drinks and similar products intended for young children, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([4]) intended for the general population, excluding infants. During the application process, the applicant agreed to also exclude young children (under 3 years of age) from the scope of the request for authorisation of the novel food in food supplements. The applicant also proposed that food supplements containing 3-FL should not be used if other foods with added 3-FL are consumed on the same day.

([1]) OJ L 327, 11.12.2015, p. 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).

([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).

([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).

(4) On 1 October 2019, the applicant also made a request to the Commission for the protection of proprietary data for a number of studies submitted in support of the application, namely, the detailed characterisation data on the production bacterial strain ([5]); the novel food production process ([6]); the analyses of the various 3-FL batches ([7]); the analytical reports on the characterisation via nuclear magnetic resonance ('NMR') of 3-FL and of the 3-FL naturally present in human milk ([8]); the 3-FL stability reports ([9]); the 3-FL intake assessment reports ([10]); a bacterial reverse mutation test ([11]); an *in vitro* mouse micronucleus test ([12]); an *in vitro* micronucleus test with Chinese hamster ovary cells ([13]); an *in vitro* mammalian cell chromosomal aberration test in human lymphocytes ([14]); an acute oral toxicity test in rats ([15]); a 90-day oral toxicity study in the rat including serum and urine analysis ([16]); a 6-day oral toxicity study in piglets ([17]); and a 3-week oral toxicity study in neonatal piglets ([18]).

(5) On 29 January 2020, the Commission, in accordance with Article 10(3) of Regulation (EU) 2015/2283 requested the European Food Safety Authority ('the Authority') to carry out an assessment of 3-FL as a novel food.

(6) On 25 May 2021, the Authority adopted its scientific opinion on the safety of 3-FL as a novel food pursuant to Regulation (EU) 2015/2283 ([19]).

(7) In its scientific opinion, the Authority concluded that 3-FL is safe under the proposed conditions of use for the proposed target populations. Therefore, that scientific opinion gives sufficient grounds to establish that 3-FL, when used in unflavoured pasteurised and unflavoured sterilised (including UHT) milk products, flavoured and unflavoured fermented milk based products including heat-treated products, cereal bars, dairy analogues and non-dairy yoghurts, beverages (flavoured drinks, energy drinks, sports drinks), infant formula and follow-on formula as defined in Regulation (EU) No 609/2013, processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013, total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013, foods for special medical purposes as defined in Regulation (EU) No 609/2013, milk based drinks and similar products intended for young children, and in food supplements as defined in Directive 2002/46/EC intended for the general population, with limitations for infants and young children complies with Article 12(1) of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority considered that it could not have reached its conclusions on the safety of the 3-FL without the data from the detailed characterisation data on the production bacterial strain; the novel food production process; the analyses of the various 3-FL batches; the analytical reports on the characterisation via NMR of 3-FL and of the 3-FL naturally present in human milk; the 3-FL stability reports; the 3-FL intake assessment reports; a bacterial reverse mutation test; an *in vitro* mouse micronucleus test; an *in vitro* micronucleus test with Chinese hamster ovary cells; an *in vitro* mammalian cell chromosomal aberration test in human lymphocytes; an acute oral toxicity test in rats; a 90-day oral toxicity study in the rat including serum and urine analysis; a 6-day oral toxicity study in piglets; and a 3-week oral toxicity study in neonatal piglets.

(9) Following the receipt of the Authority's scientific opinion, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the data from the detailed characterisation data on the production bacterial strain; the novel food production process; the analyses of the various 3-FL batches; the analytical reports on the characterisation via NMR of 3-FL and of the 3-FL naturally present in human milk; the 3-FL stability reports; the 3-FL intake assessment reports; a bacterial reverse mutation test; an *in vitro* mouse micronucleus test; an *in vitro* micronucleus test with Chinese hamster ovary cells; an *in vitro* mammalian cell chromosomal aberration test in human lymphocytes; an acute oral toxicity test in rats; a 90-day oral toxicity study in the rat including serum and urine analysis; a 6-day oral toxicity study in piglets; and a 3-week oral toxicity study in neonatal piglets.

([5]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([6]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([7]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([8]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([9]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([10]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([11]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished); J. Pitt et al., 2019 Food and Chemical Toxicology, 134.
([12]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished); J. Pitt et al., 2019 Food and Chemical Toxicology, 134.
([13]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished); J. Pitt et al., 2019 Food and Chemical Toxicology, 134.
([14]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished); J. Pitt et al., 2019 Food and Chemical Toxicology, 134.
([15]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished); J. Pitt et al., 2019 Food and Chemical Toxicology, 134.
([16]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished); J. Pitt et al., 2019 Food and Chemical Toxicology, 134.
([17]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([18]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([19]) Safety of 3-Fucosyllactose (3-FL) as a novel food pursuant to Regulation (EU) 2015/2283; *EFSA Journal* 2021;19(6):6662.

(10) The applicant declared that, at the time the application was made, they held proprietary and exclusive rights of reference to the studies under national law and that therefore third parties could not lawfully access or use those studies.

(11) 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. Therefore, the data contained in the applicant's file which served as a basis for the Authority to establish the safety of the novel food and to reach its conclusions on the safety of 3-FL, 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 any subsequent applicant for a period of 5 years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of 3-FL should be restricted to the applicant for that period.

(12) However, restricting the authorisation of 3-FL and of the reference to the data contained in the applicant's file for the sole use by 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 such authorisation under Regulation (EU) 2015/2283.

(13) In line with the conditions of use of food supplements containing 3-FL as proposed by the applicant and assessed by the Authority, it is necessary to inform consumers through the use of an appropriate label that food supplements containing 3-FL should not be consumed on the same day with other foods containing added 3-FL.

(14) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(15) 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. 3-Fucosyllactose (3-FL) 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 5 years from the date of entry into force of this Regulation only the initial applicant:

Company: DuPont Nutrition & Biosciences ApS;

Address: Langebrogade 1, 1001 Copenhagen K, 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 that novel food without reference to the data protected pursuant to Article 2 or with the agreement of the applicant.

3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex.

Article 2

The studies contained in the application file on the basis of which the novel food referred to in Article 1 have been assessed by the Authority, claimed by the applicant as proprietary and without which the novel food could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of DuPont Nutrition & Biosciences ApS.

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, 19 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

1. in Table 1 (Authorised novel foods), the following entry is inserted:

'Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
3-Fucosyllactose (3-FL) (microbial source)	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be '3-Fucosyllactose'. The labelling of food supplements containing 3-Fucosyllactose (3-FL) shall bear a statement that they should not be consumed: a) if foods containing added 3-Fucosyllactose are consumed on the same day; b) by infants and children under 3 years of age.		Authorised on 12 December 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: DuPont Nutrition & Biosciences ApS Langebrogade 1, 1001 Copenhagen K, Denmark. During the period of data protection, the novel food 3-Fucosyllactose is authorised for placing on the market within the Union only by DuPont Nutrition & Biosciences ApS, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of DuPont Nutrition & Biosciences ApS. End date of the data protection: 12 December 2026.'
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0,85 g/L			
	Unflavoured and flavoured fermented milk-based products including heat-treated products	0,5 g/L (beverages)			
		5,0 g/kg (products other than beverages)			
	Dairy analogues	0,85 g/L (beverages)			
		8,5 g/kg (products other than beverages)			
	Flavoured drinks, energy and sports drinks	1,0 g/L			
	Cereal bars	30,0 g/kg			
	Infant formula as defined under Regulation (EU) No 609/2013	0,85 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined under Regulation (EU) No 609/2013	0,85 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Milk-based drinks and similar products intended for young children	0,85 g/L (beverages) 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 under Regulation (EU) No 609/2013	0,3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
		3,0 g/kg for products other than beverages			
	Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	2,0 g/L (beverages)			
		30,0 g/kg (products other than beverages)			
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food Supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	5,0 g/day			

2. in Table 2 (Specifications), the following entry is inserted:

'Authorised Novel Food	Specification
3-Fucosyllactose ('3-FL') (microbial source)	**Description:** 3-Fucosyllactose (3-FL) is a purified, white to off-white powder that is produced by microbial fermentation and contains limited levels of D-Lactose, L-Fucose, D-Galactose, and D-Glucose. **Source:** Genetically modified strain of *Escherichia coli* K-12. **Definition:** Chemical formula: $C_{18}H_{32}O_{15}$ Chemical name: β-D-galactopyranosyl-(1 → 4)[-α-L-fucopyranosyl-(1 → 3)]-D-glucopyranose Molecular mass: 488,44 Da CAS No 41312-47-4 **Characteristics/Composition:** 3-Fucosyllactose (% of dry matter): ≥ 90,0 % (w/w) D-Lactose (% of dry matter): ≤ 5,0 % (w/w) L-Fucose (% of dry matter): ≤ 3,0 % (w/w) Sum of D-Galactose/D-Glucose (% of dry matter): ≤ 3,0 % (w/w) Sum of other carbohydrates[a] (% of dry matter): ≤ 3,0 % (w/w)

	Moisture: ≤ 5,0 % (w/w) pH (20 °C, 5 % solution): 3,0-7,5 Residual protein: ≤ 0,01 % (w/w) Ash (%): ≤ 0,5 **Heavy metals/Contaminants:** Arsenic: ≤ 0,2 mg/kg Cadmium: ≤ 0,05 mg/kg Lead: ≤ 0,05 mg/kg Mercury: ≤ 0,1 mg/kg Aflatoxin M1: ≤ 0,025 µg/kg Aflatoxin B1: ≤ 0,1 µg/kg Residual endotoxins: ≤ 0,3 EU/mg **Microbiological criteria:** Total plate count: ≤ 1 000 CFU/g Enterobacteriaceae: Absence in 10 g *Salmonella* sp.: Absence in 25 g *Cronobacter (Enterobacter) sakazakii*: Absence in 10 g *Listeria monocytogenes*: Absence in 25 g *Bacillus cereus*: ≤ 10 CFU/g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g CFU: Colony Forming Units; EU: Endotoxin Units; [a]Sum of other carbohydrates: 3-Fucosyllactose isomer, difucosyllactose isomer, and oligomers.’