Official Journal
of the European Union

EN
L series

2025/1537

30.7.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1537

of 29 July 2025

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food '3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21 (DE3)'

(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 of novel foods 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]) has established a Union list of novel foods.

(3) Commission Implementing Regulation (EU) 2023/52 ([3]) authorised the placing on the market of '3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21 (DE3)' for use in infant formula, follow-on formula, processed cereal-based foods for infants and young children, and baby foods for infants and young children, as defined under Regulation (EU) No 609/2013 of the European Parliament and of the Council ([4]), milk based drinks and similar products intended for young children, foods for special medical purposes for infants and young children as defined under Regulation (EU) No 609/2013, foods for special medical purposes as defined under Regulation (EU) No 609/2013, excluding foods for infants and young children, and food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([5]), for the general population, excluding infants and young children.

(4) On 25 April 2024, the company Chr. Hansen A/S ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change of the conditions of use of the novel food '3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21 (DE3)'. The applicant requested to increase the maximum authorised use levels of '3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21 (DE3)' in infant formula, follow-on formula and foods for special medical purposes for infants and young children as defined in Regulation (EU) No 609/2013, from the current levels of 0,9 g/L, 0,9 g/L and 1,2 g/L respectively to

([1]) OJ L 327, 11.12.2015, p. 1, ELI: http://data.europa.eu/eli/reg/2015/2283/oj.

([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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

([3]) Commission Implementing Regulation (EU) 2023/52 of 4 January 2023 authorising the placing on the market of 3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21(DE3) as a novel food and amending Implementing Regulation (EU) 2017/2470 (OJ L 3, 5.1.2023, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2023/52/oj).

([4]) 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, ELI: http://data.europa.eu/eli/reg/2013/609/oj).

([5]) 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, ELI: http://data.europa.eu/eli/dir/2002/46/oj).

1,75 g/L for all three food categories. The applicant also requested to increase the maximum authorised use level of '3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21 (DE3)' in food supplements as defined in Directive 2002/46/EC intended for the general population, excluding infants and young children, from the currently authorised level of 3,0 g/day to 4,0 g/day.

(5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 24 June 2024, requesting it to provide a scientific opinion on the changes of the conditions of use of '3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21 (DE3)' as a novel food.

(6) On 24 March 2025, the Authority adopted its scientific opinion on the 'safety of the extension of use of 3-fucosyllactose (3-FL) as a novel food pursuant to Regulation (EU) 2015/2283' ([6]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that the proposed change is safe under the proposed conditions of use, and therefore it is appropriate to amend the conditions of use of '3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21 (DE3)'.

(8) The information provided by the applicant and the Authority's opinion give sufficient grounds to establish that the changes to the conditions of use of '3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21 (DE3)' are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.

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

(10) 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

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

Article 2

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, 29 July 2025.

For the Commission
The President
Ursula VON DER LEYEN

([6]) *EFSA Journal*, https://doi.org/10.2903/j.efsa.2025.9370.

ANNEX

In Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for '3-Fucosyllactose ('3-FL') (produced by a derivative strain of *E. coli* BL21(DE3)' is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
	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 (a) they should not be consumed by children under 3 years of age; (b) they should not be used if other foods containing added 3-Fucosyllactose are consumed on the same day.		Authorised on 25 January 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: "Chr. Hansen A/S", Bøge Allé 10-12, 2970 Hørsholm, Denmark. During the period of data protection, the novel food 3-Fucosyllactose is authorised for placing on the market within the Union only by Chr. Hansen A/S 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 "Chr. Hansen A/S". End date of the data protection 25 January 2028.'
'**3-Fucosyllactose ("3-FL") (produced by a derivative strain of *E. coli* BL21 (DE3))**	Infant formula as defined under Regulation (EU) No 609/2013	1,75 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	1,75 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Processed cereal-based foods for infants and young children and baby foods for infants and young children as defined under Regulation (EU) No 609/2013	1,20 g/l or 1,20 g/kg 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	1,20 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
	Foods for special medical purposes for infants and young children as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the infants and young children for whom the products are intended but in any case not higher than 1,75 g/l or 1,75 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children	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, for the general population, excluding infants and young children	4 g/day			

ELI: http://data.europa.eu/eli/reg_impl/2025/1537/oj