COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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 as defined under Regulation (EU) No 609/2013[4],

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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

follow-on formula as defined under Regulation (EU) No 609/2013, 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, 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[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 of Regulation (EU) 2015/2283 to change 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) 609/2013, from the current levels of 0.9 g/L and 1.2 g/L respectively to 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[4] 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 in 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]. That scientific opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(7) In its opinion, the Authority concluded that '3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21 (DE3)' is safe under the proposed conditions of use. Therefore, the opinion of the Authority gives sufficient grounds to establish that '3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21 (DE3)', under the specific conditions of use, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

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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)

6 EFSA Journal. 2025;23:e9370

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

(9) 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,

For the Commission
The President
Ursula VON DER LEYEN