COMMISSION IMPLEMENTING REGULATION (EU) 2023/1582

of 1 August 2023

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food 3′-Sialyllactose sodium salt produced by derivative strains 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) 2021/96 ([3]) authorised the placing on the Union market of 3′-Sialyllactose sodium salt obtained by microbial fermentation using the genetically modified strain K-12 DH1 of *Escherichia coli ('E. coli')* as a novel food under Regulation (EU) 2015/2283.

(4) Commission Implementing Regulation (EU) 2023/113 ([4]) authorised the placing on the Union market of 3′-Sialyllactose sodium salt obtained by microbial fermentation using genetically modified derivative strains of *E. coli* BL21(DE3) as a novel food under Regulation (EU) 2015/2283.

(5) On 8 February 2023, 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 3′-Sialyllactose ('3′-SL') sodium salt, obtained by microbial fermentation using genetically modified derivative strains (a production strain and an optional degradation strain) of *E. coli* BL21(DE3). The applicant requested for an increase of the maximum levels of 3′-SL sodium salt used in infant formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([5]), from the currently maximum authorised level of 0,23 g/kg or l to a

([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]) Commission Implementing Regulation (EU) 2021/96 of 28 January 2021 authorising the placing on the market of 3'-sialyllactose sodium salt 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 (OJ L 31, 29.1.2021, p. 201).

([4]) Commission Implementing Regulation (EU) 2023/113 of 16 January 2023 authorising the placing on the market of 3'-sialyllactose sodium salt produced by derivative strains of *Escherichia coli* BL21(DE3) as a novel food and amending Implementing Regulation (EU) 2017/2470 (OJ L 15, 17.1.2023, p. 1).

([5]) 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).

maximum level of 0,28 g/kg or l, and to extend the use of 3′-SL sodium salt in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([6]) intended for infants and young children at the levels of 0,28 g/day. Subsequently, on 23 March 2023, the applicant modified the initial request in the application and removed from the proposed uses the use of 3′-SL sodium salt in food supplements intended for infants and young children.

(6) The applicant justified the request for the proposed changes in the conditions of use of 3′-SL sodium salt in infant formula as defined in Regulation (EU) No 609/2013, as a means to bring the use levels of 3′-SL sodium salt in infant formula and the resulting intakes closer to the levels of 3′-SL naturally found in human milk.

(7) The Commission considers that the requested update of the Union list concerning the change of the conditions of use of 3′-SL sodium salt produced by derivative strains of *E. coli* BL21(DE3) as proposed by the applicant, is not liable to have an effect on human health and that a safety evaluation by the European Food Safety Authority ('the Authority') in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. In this regard, the slightly increased intake of 3′-SL sodium salt that would result from this increased use in infant formula as defined in Regulation (EU) No 609/2013, would still be lower than the intakes of 3′-SL from breast milk that were considered by the Authority to be of no safety concern in its 2022 opinion of 3′-SL sodium salt produced by derivative strains of *E. coli* BL21(DE3). ([7]) The Commission also considers that the increase in the maximum use levels of 3′-SL sodium salt in infant formula from 0,23 g/kg or l to 0,28 g/kg or l should also be reflected in the conditions of use of foods for special medical purposes for infants and young children as defined under Regulation (EU) No 609/2013, as the maximum levels of 3′-SL sodium salt in those foods are linked to the maximum levels used in infant formula.

(8) The information provided in the application and the Authority's opinion of 2022 give sufficient grounds to establish that the changes to the conditions of use of 3′-SL sodium salt produced by derivative strains of *E. coli* strain 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*.

([6]) 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).

([7]) *EFSA Journal* 2022;20(5):7331.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 1 August 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex to Implementing Regulation (EU) 2017/2470, in Table 1 (Authorised novel foods), the entry for 3′-Sialyllactose ('3′-SL') sodium salt (produced by derivative strains 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′-Sialyllactose sodium salt'. The labelling of food supplements containing 3′-Sialyllactose (3′-SL) sodium salt 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′-sialyllactose sodium salt are consumed the same day.		Authorised on 6 February 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", Boege Allé 10-12, 2970 Hoersholm, Denmark. During the period of data protection, the novel food 3′-Sialyllactose sodium salt 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: 6 February 2028.'
'3′-Sialyllactose ('3′-SL') sodium salt (produced by derivative strains of *E. coli* BL21(DE3))	Infant formula as defined under Regulation (EU) No 609/2013	0,28 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	0,28 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	0,28 g/L or 0,28 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	0,28 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

	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 0,28 g/L or 0,28 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	0,7 g/day			