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

(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 28 February 2019, the company Glycom A/S ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place 3'-sialyllactose ('3'-SL') sodium salt, obtained by microbial fermentation with a genetically modified strain of *Escherichia coli,* strain K12 DH1, on the Union market as a novel food. The applicant requested for 3'-SL sodium salt to be used as a novel food in unflavoured pasteurised and unflavoured sterilised milk products, flavoured and unflavoured fermented milk based products including heat-treated products, beverages (flavoured drinks excluding drinks with a pH less than 5), cereal bars, infant formula and follow-on formula, processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([3]), milk-based drinks and similar products intended for young children, 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, 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 and young children. The applicant also proposed that food supplements containing 3'-SL sodium salt should not be used if other foods with added 3'-SL sodium salt, are consumed on the same day.

(4) On 28 February 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 proprietary analytical reports on the structure comparison via nuclear magnetic resonance ('NMR') of 3'-SL produced by bacterial fermentation with 3'-SL naturally present in human milk ([5]); the detailed characterisation data on the production bacterial strains ([6])

([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).

([5]) Glykos Finland LTD 2019 (unpublished).

([6]) Glycom 2019 (unpublished).

and their certificates ([7]); the specifications for the raw materials and processing aids ([8]); the certificates of analyses of the various 3'-SL sodium salt batches ([9]); the analytical methods and validation reports ([10]); the 3'-SL sodium salt stability reports ([11]); the detailed description of the production process ([12]); the laboratory accreditation certificates ([13]); the 3'-SL intake assessment reports ([14]); an *in vitro* mammalian cell micronucleus test with 3'-SL sodium salt ([15]); an *in vitro* mammalian cell micronucleus test with the related compound 6'-sialyllactose ('6'-SL') sodium salt ([16]); a bacterial reverse mutation test with 3'-SL sodium salt ([17]); a bacterial reverse mutation test with 6'-SL sodium salt ([18]); a 14-day oral toxicity study in the neonatal rat with 3'-SL sodium salt ([19]); a 90-day oral toxicity study in the neonatal rat with 3'-SL sodium salt including the summary table of the statistically significant observations ([20]), a 14-day oral toxicity study in the neonatal rat with 6'-SL sodium salt ([21]), and a 90-day oral toxicity study in the neonatal rat with 6'-SL sodium salt, including the summary table of the statistically significant observations ([22]).

(5) On 12 June 2019, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of 3'-SL sodium salt as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.

(6) On 25 March 2020, the Authority adopted its scientific opinion 'Safety of 3'-Sialyllactose (3'-SL) sodium salt as a novel food pursuant to Regulation (EU) 2015/2283' ([23]).

(7) In its scientific opinion, the Authority concluded that 3'-SL sodium salt is safe under the proposed conditions of use for the proposed target populations. Therefore, that scientific opinion gives sufficient grounds to establish that 3'-SL sodium salt, when used in unflavoured pasteurised and unflavoured sterilised milk products, flavoured and unflavoured fermented milk based products including heat-treated products, beverages (flavoured drinks excluding drinks with a pH less than 5), cereal bars, infant formula and follow-on formula, processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013, milk-based drinks and similar products intended for young children, 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, and in food supplements as defined in Directive 2002/46/EC, 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'-SL sodium salt without the data from the proprietary analytical reports on the structure comparison via NMR of 3'-SL produced by bacterial fermentation with 3'-SL naturally present in human milk; the detailed characterisation data on the production bacterial strains and their certificates; the specifications for the raw materials and processing aids, the certificates of analyses of the various 3'-SL sodium salt batches; the analytical methods and validation reports; the 3'-SL sodium salt stability reports; the detailed description of the production process; the laboratory accreditation certificates; the 3'-SL intake assessment reports; the *in vitro* mammalian cell micronucleus test with 3'-SL sodium salt; the bacterial reverse mutation test with 3'-SL sodium salt; the 14-day oral toxicity study in the neonatal rat with 3'-SL sodium salt; and the 90-day oral toxicity study in the neonatal rat with 3'-SL sodium salt, including the summary table of the statistically significant observations.

([7]) Glycom/DSMZ 2018 (unpublished).
([8]) Glycom 2019 (unpublished).
([9]) Glycom 2019 (unpublished).
([10]) Glycom 2019 (unpublished).
([11]) Glycom 2019 (unpublished).
([12]) Glycom 2018 (unpublished).
([13]) Glycom 2019 (unpublished).
([14]) Glycom 2019 (unpublished).
([15]) Gilby 2019 (unpublished).
([16]) Gilby 2018 (unpublished).
([17]) Šoltésová, 2019 (unpublished).
([18]) Šoltésová, 2018 (unpublished)
([19]) Stannard 2019a (unpublished).
([20]) Stannard 2019b (unpublished).
([21]) Flaxmer 2018a (unpublished).
([22]) Flaxmer 2018b (unpublished).
([23]) *EFSA Journal* 2020;18(5):6098

(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 analytical reports on the structure comparison via nuclear magnetic resonance ('NMR') of 3'-SL produced by bacterial fermentation with 3'-SL naturally present in human milk; the detailed characterisation data on the production bacterial strains and their certificates; the specifications for the raw materials and processing aids; the certificates of analyses of the various 3'-SL sodium salt batches; the analytical methods and validation reports; the 3'-SL sodium salt stability reports; the detailed description of the production process; the laboratory accreditation certificates; the 3'-SL intake assessment reports; the *in vitro* mammalian cell micronucleus test with 3'-SL sodium salt; the bacterial reverse mutation test with 3'-SL sodium salt; the 14-day oral toxicity study in the neonatal rat with 3'-SL sodium salt; and the 90-day oral toxicity study in the neonatal rat with 3'-SL sodium salt, including the summary table of the statistically significant observations, and to clarify their claim to an exclusive right of reference to these studies, as referred to in Article 26(2)(b) of Regulation (EU) 2015/2283.

(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'-SL sodium salt, 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 five years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of 3'-SL sodium salt should be restricted to the applicant for that period.

(12) However, restricting the authorisation of 3'-SL sodium salt 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'-SL sodium salt as proposed by the applicant and assessed by the Authority, it is necessary to inform consumers with an appropriate label that food supplements containing 3'-SL sodium salt should not be consumed the same day if other foods with added 3'-SL sodium salt are consumed on the same day.

(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'-Sialyllactose (3'-SL) sodium salt 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 five years from the date of entry into force of this Regulation only the initial applicant:

Company: Glycom A/S;

Address: Kogle Allé 4, DK-2970 Hørsholm, 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 data contained in the application file on the basis of which 3'-sialyllactose sodium salt has been assessed by the Authority, claimed by the applicant as fulfilling the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283, shall not be used for the benefit of any subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of the applicant.

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, 28 January 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 in alphabetical order:

'Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
3'-Sialyllactose (3'-SL) sodium salt (microbial source)	***Specified food category***	***Maximum levels (expressed as 3'- Sialyllactose)***	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 sodium salt shall bear a statement that they should not be consumed: a) if foods containing added 3'-Sialyllactose sodium salt are consumed the same day. b) by infants and young children		Authorised on 18 February 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Glycom A/S, Kogle Allé 4, DK-2970 Hørsholm, 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 Glycom 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 Glycom A/S. End date of the data protection: 18 February 2026.'
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0,25 g/L			
	Flavoured fermented milk-based products including heat-treated products	0,25 g/L (beverages)			
		0,5 g/kg (products other than beverages)			
	Unflavoured fermented milk-based products	0,25 g/L (beverages)			
		2,5 g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0,25 g/L			
	Cereal bars	2,5 g/kg			
	Infant formula as defined under Regulation (EU) No 609/2013	0,2 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	0,15 g/L 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	0,15 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

		1,25 g/kg for products other than beverages			
	Milk-based drinks and similar products intended for young children	0,15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	0,5 g/L (beverages)			
		5 g/kg (products other than beverages)			
	Food 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	0,5 g/day			

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

'Authorised Novel Food	Specification
3'-Sialyllactose (3'-SL) sodium salt (microbial source)	**Description:** 3'-Sialyllactose (3'-SL) sodium salt is a purified, white to off-white powder or agglomerate that is produced by a microbial process and contains limited levels of lactose, 3'-sialyl-lactulose, and sialic acid **Source:** Genetically modified strain of *Escherichia coli* K-12 DH1

	Definition: Chemical formula: $C_{23}H_{38}NO_{19}Na$ Chemical name: N-Acetyl-α-D-neuraminyl-(2→3)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt Molecular mass: 655,53 Da CAS No 128596-80-5 **Characteristics/Composition:** Appearance: White to off-white powder or agglomerate Sum of 3'-Sialyllactose sodium salt, D-Lactose, and Sialic acid (% of dry matter): ≥ 90,0 % (w/w) 3'-Sialyllactose sodium salt (% of dry matter): ≥ 88,0 % (w/w) D-Lactose: ≤ 5,0 % (w/w) Sialic acid: ≤ 1,5 % (w/w) 3'-Sialyl-lactulose: ≤ 5,0 % (w/w) Sum of other carbohydrates: ≤ 3,0 % (w/w) Moisture: ≤ 8,0 % (w/w) Sodium: 2,5 – 4,5 % (w/w) Chloride: ≤ 1,0 % (w/w) pH (20 °C, 5 % solution): 4,5 -6,0 Residual protein: ≤ 0,01 % (w/w) **Microbiological criteria:** Aerobic mesophilic bacteria total plate count: ≤ 1000 CFU/g *Enterobacteriaceae*: ≤ 10 CFU/g *Salmonella* sp.: Absence in 25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg

CFU: Colony Forming Units; EU: Endotoxin Units'