NWSI 2026 No.51

FOOD

REGULATED PRODUCTS

NOVEL FOODS

Determination of authorisation status: authorisation of 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) as a novel food

Explanatory note

(this note is not part of the determination)

This determination is made in relation to Wales by the Welsh Ministers in exercise of the powers conferred by Article 12(1) of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (EUR 2015/2283).

3'-Sialyllactose (3'-SL) sodium salt produced from a microbial source (*Escherichia coli* K-12 DH1) is already authorised as a novel food in Wales as '3'-Sialyllactose (3'-SL) sodium salt (microbial source)'. The terms of that authorisation and specification continue to have effect, as they had effect on 31 March 2025, pursuant to regulation 23 (savings and transitional provision: general) of the Food and Feed (Regulated Products) (Amendment, Revocation, Consequential and Transitional Provision) Regulations 2025 and can be accessed on the Register of Novel Food Authorisations.

This determination authorises, in relation to Wales, 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) as a novel food. The terms of authorisation and the conditions, requirements and specification upon which the novel food is authorised are set out in the Schedule.

There has been consultation as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (EUR 2002/178).

Determination

Application and coming into force

1. This determination applies in relation to Wales, and comes into force on [DATE].

Interpretation

2. In this determination:

   "Regulation 1169/2011" means Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (EUR 2011/1169);

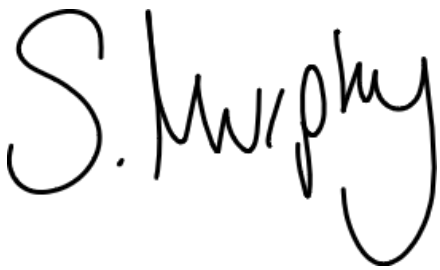
   "Regulation 609/2013" means Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control etc. (EUR 2013/609);

   "Regulation 2015/2283" means Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (EUR 2015/2283)

3. Any expression used both in this determination and in Regulation 2015/2283 has the same meaning as it has in that Regulation.

Determination of authorisation status of 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637))

4. 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637)) is authorised as a novel food to be placed on the market in Wales, and to be used in or on the food, in accordance with the conditions, requirements and specification set out in the Schedule.



5 March 2026

SCHEDULE

Authorised novel food	**Conditions under which the novel food may be used**		**Additional specific labelling requirements**	**Data protection**
	Specified food category	*Maximum levels*		
3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli* W (ATCC 9637))	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.25 g/l	**1.** The designation of the novel food on the labelling of the food containing it is: '3'- Sialyllactose sodium salt' **2.** The labelling of food supplements containing 3'-Sialyllactose sodium salt must bear a statement that the supplements should not be consumed if food with added 3'- Sialyllactose sodium salt is consumed on the same day. **3.** The labelling of food supplements containing 3'-Sialyllactose sodium salt intended for infants and young children must bear a statement that they should not be consumed if breast milk or food with added 3'-Sialyllactose sodium salt is consumed on the same day.	This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation 2015/2283. Applicant: Kyowa Hakko Bio Co., Ltd.,1-9-2, Otemachi, Chiyoda-ku, Tokyo, 100-0004, Japan During the period of data protection, 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of *Escherichia coli W* (ATCC 9637)) is authorised for placing on the market, within Wales, only by Kyowa Hakko Bio Co., Ltd., unless a subsequent applicant obtains authorisation for the novel
	Unflavoured fermented milk-based products	0.25 g/l (beverages) 0.5 g/kg (products other than beverages)		
	Flavoured fermented milk-based products including heat-treated products	0.25 g/l (beverages) 2.5 g/kg (products other than beverages)		
	Cereal bars	2.5 g/kg		
	Infant formula as defined in Regulation 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 in Regulation 609/2013	0.15 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	The food information must be presented in accordance with the provisions of Regulation 1169/2011 which apply to mandatory food information.	food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation 2015/2283 or with the agreement of Kyowa Hakko Bio Co., Ltd. The data protection will expire at the end of [insert date- 5 years from authorisation].
	Processed cereal-based food and baby food for infants and young children as defined in Regulation 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 (products other than beverages)		
	Milk-based drinks and similar products intended for young children (persons aged between 1 year (12 months) up to the age of 3 years (36 months))	0.15 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Foods for special medical purposes as defined in Regulation 609/2013	In accordance with the particular nutritional requirements of the persons for whom		

		the products are intended		
	Total diet replacement for weight control as defined in Regulation 609/2013	0.5 g/l (beverages) 5 g/kg (products other than beverages)		
	Flavoured drinks (excluding cola flavour and cola flavoured drinks)	0.25 g/l		
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 excluding food supplements for infants (persons under the age of 1 year (12 months) and young children (persons aged between 1 year (12 months) up to the age of 3 years (36 months))	1.0 g/l day		
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 for young children (persons aged between 1 year (12	0.15 g/day		

	months) up to the age of 3 years (36 months))			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 for infants (persons under the age of 1 year (12 months))	0.2 g/day		

Specification

Description:

- 3'-Sialyllactose (3'-SL) sodium salt is a water-soluble white to off-white powder composed of ≥ 82.0% w/w dry matter (DM) of 3'-SL sodium salt

Source: Genetically modified strain of *Escherichia* coli W (ATCC 9637)

Definition:

- Chemical formula: $C_{23}H_{38}NO_{19}Na$
- Chemical name: sodium;(2S,4S,5R,6R)-5-acetamido-2-[(2R,3S,4S,5R,6S)-3,5-dihydroxy-2-(hydroxymethyl)-6-[(2R,3S,4R,5R)-4,5,6-trihydroxy-2-(hydroxymethyl)oxan-3-yl]oxyoxan-4-yl]oxy-4-hydroxy-6-[(1R,2R)-1,2,3-trihydroxypropyl]oxane-2-carboxylate
- CAS number: 128596-80-5
- Molecular mass: 655.53 Da

Characteristics/composition:

- 3'-Sialyllactose sodium salt ≥ 82.0 % w/w dry matter

- Sialic acid ≤ 6.0 % w/w dry matter
- D-glucose ≤ 3.0 % w/w dry matter
- D-lactose ≤ 3.0 % w/w dry matter
- Sum of 3'-sialyllactulose and 6′-Sialyllactose sodium salt ≤ 5.0 % w/w dry matter
- Sum of other carbohydrates* ≤ 12.0 % w/w dry matter
- Water ≤ 10.5 % w/w
- Residual Protein ≤ 0.01 % w/w
- Sodium ≤ 5.0 % w/w dry matter
- pH (5% solution, 25°C) 4.5 – 7.5

*(sum of other carbohydrates = 100 % w/w of dry matter – 3′-Sialyllactose (acid, % w/w of dry matter) –quantified carbohydrates ((% w/w of dry matter), Sialic acid + D-Lactose + D-Glucose + (3′- Sialyllactulose and 6′-Sialyllactose (acids)) – sodium (w/w of dry matter))

Heavy metals and contaminants:

- Arsenic: ≤ 0.2 mg/kg
- Cadmium: ≤ 0.2 mg/kg
- Lead: ≤ 0.02 mg/kg
- Mercury: ≤ 0.1 mg/kg
- Aflatoxin M1: ≤ 0.025 µg/kg

Microbiological criteria:

- Aerobic plate count: ≤ 1000 CFU/g
- Yeast and mould: ≤ 100 CFU/g
- *Enterobacteriaceae*: Absent in 10g
- *Salmonella* spp.: Absent in 25g
- *Cronobacter* spp.: Absent in 10g
- *Listeria monocytogenes:* Absent in 25g
- Presumptive *Bacillus cereus:* ≤ 50 CFU/g

- Residual Endotoxins: ≤ 10 EU/mg

CFU: Colony Forming Units
EU: Endotoxin Units