

## **WG25-62**

### **FOOD, WALES**

#### **REGULATED PRODUCTS, WALES**

##### **NOVEL FOODS**

Determination of authorisation status: authorisation of new uses, and consolidation of existing uses, for Isomaltooligosaccharide 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 of Regulation ([EU](#) 2015/2283) of the European Parliament and of the Council on novel foods (EUR 2015/2283).

It authorises Isomaltooligosaccharide (also known as oligo-isomaltose) as a novel food for use in sixteen new food categories: ice cream and dairy desserts; instant coffee and instant tea; table-top sweeteners; cakes; shortcrust (pies and tarts); pastries; breakfast cereals; condiments, relishes, gravies and savoury sauces; gelatine desserts; fruit pie fillings; fruit spreads; yoghurts; milk-based drinks; potato cereal, flour or starch-based snacks; dessert sauces and toppings; food supplements for persons aged 10 and above. The terms of the authorisation and the conditions, requirements and specification upon which the novel food is authorised are set out in the Schedule.

In relation to the new authorised uses, 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).

This determination also consolidates, and replaces, the authorisation of the placing on the market of Isomaltooligosaccharide and all existing authorised uses of this novel food, replacing the existing authorisation that, prior to this determination, had effect pursuant to regulation 23 (savings and transitional provision: general) of the Food and Feed (Regulated Products) (Amendment, Revocation, Consequential and Transitional Provision) Regulations 2025. There are no changes to the scope of the existing authorised uses, but wording is updated and clarified, including:

- the food category “fruit juices” is updated to “fruit-based drinks” to avoid inconsistency with definitions in the Fruit Juices and Fruit Nectars (Wales) Regulations 2013;
  - the food category “foods intended to meet the expenditure of intense muscular efforts, especially for sportsmen (including isotonic drinks)” is updated to refer to “sports people”;
  - the food categories “cereals bars” and “breakfast cereal bars” have been combined within a consolidated category of “cereal bars”;
  - the maximum levels for the conditions under which the novel food may be used are updated so as to be expressed as “% w/v” (percent weight/volume) for liquids and “% w/w” (percent weight/weight) for non-liquids.
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## **Determination**

### **Application and coming into force**

1. This determination applies in relation to Wales, and comes into force on 13<sup>th</sup> October 2025.

### **Interpretation**

2. Any expression used both in this determination and in Regulation (EU) No 2015/2283 of the European Parliament and of the Council on novel foods has the same meaning as it has in that Regulation.

### **Determination of authorisation status of Isomaltooligosaccharide**

3. Isomaltooligosaccharide is authorised as a novel food to be placed on the market in Wales, and to be used in or on the food categories specified in the Schedule, in accordance with the conditions, requirements and specification set out in the Schedule.
4. This determination consolidates and replaces the existing authorisation for Isomaltooligosaccharide.

Sarah Murphy

Minister for Mental Health and Wellbeing, under the authority of the Cabinet Secretary for Health and Social Care, one of the Welsh Ministers

6 October 2025

## SCHEDULE

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Data protection
	Specified food category	Maximum levels (% w/v liquids) (% w/w non-liquids)		
Isomaltooligosaccharide	Energy-reduced soft drinks	6.5% w/v	<p><b>1.</b> The designation of the novel food on the labelling of the food containing it is:</p> <p style="text-align: center;">“Isomaltooligosaccharide”</p> <p><b>2.</b> The designation of the novel food on the labelling must be accompanied by indication that the Isomaltooligosaccharide is a source of glucose.</p> <p><b>3.</b> The labelling of food supplements containing Isomaltooligosaccharide must bear a statement that the food supplement is not to be consumed by children under 10 years of age.</p>	<p>This data protection provision applies only to the use of Isomaltooligosaccharide in the following food categories:</p> <ul style="list-style-type: none"> <li>• ice cream, dairy desserts;</li> <li>• instant coffee, instant tea;</li> <li>• table-top sweeteners;</li> <li>• cakes;</li> <li>• shortcrust (pies and tarts);</li> <li>• pastries;</li> <li>• breakfast cereals;</li> <li>• condiments, relishes, gravies, savoury sauces;</li> <li>• gelatine desserts;</li> <li>• fruit pie fillings;</li> </ul>
	Energy drinks	5.0% w/v		
	Foods intended to meet the expenditure of intense muscular efforts, especially for sports people (including isotonic drinks)	6.5% w/w  6.5% w/v		
	Fruit-based drinks	5 % w/v		
	Processed vegetables; vegetable juices	5% w/v		
	Other soft drinks	5% w/v		
	Cookies, biscuits	20% w/w		
	Cereal bars	25 % w/w		
	Hard candies	97 % w/w		

Soft candies/ chocolate bars	25 % w/w	<p>The food information must be presented in accordance with the provisions of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (EUR 2011/1169) which apply to mandatory food information.</p>	<ul style="list-style-type: none"> <li>• fruit spreads;</li> <li>• yoghurts;</li> <li>• milk-based drinks;</li> <li>• potato, cereal, flour, starch-based snacks;</li> <li>• dessert sauces, and toppings;</li> <li>• food supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for children under 10 years of age</li> </ul> <p>This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: BioNeutra North America Inc., 9608 25 Avenue NW. Edmonton, Alberta T6N 1J4. Canada.</p> <p>During the period of data protection, the use of Isomaltooligosaccharide within the listed food categories, is authorised for placing on the market, within Wales, only by BioNeutra North America Inc. unless a subsequent applicant obtains authorisation for the novel food without reference to</p>
Meal replacement for weight control (as bars or milk-based)	20 % w/w		
Ice cream, dairy desserts	8% w/w		
Instant coffee, instant tea	10% w/w		
Table-top sweeteners	≤100% w/w		
Cakes	20% w/w		
Shortcrust (pies and tarts)	20% w/w		
Pastries	15% w/w		
Breakfast cereals	10% w/w		
Condiments, relishes, gravies, savoury sauces	10% w/w		
Gelatine desserts	15% w/w		
Fruit pie fillings	15% w/w		
Fruit spreads	50% w/w		
Yoghurts	2.5% w/w		
Milk-based Drinks	5% w/v		
Potato, cereal, flour, starch-based snacks	5% w/w		

	Dessert sauces, and toppings	50% w/v		the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of BioNeutra North America Inc.  The data protection will expire at the end of 12 <sup>th</sup> October 2030.
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for children under 10 years of age	<100% w/w		

### Specification

**Powder:**

- Solubility (water) (%): > 99
- Glucose (% dry basis): ≤ 5.0
- Isomaltose + DP3 to DP9 (% dry basis): ≥ 90
- Moisture (%): ≤ 4.0
- Sulphated ash (g/100 g): ≤ 0.3
- Heavy metals:
  - Lead (mg/kg): ≤ 0.5
  - Arsenic (mg/kg): ≤ 0.5

**Syrup:**

- Dried solids (g/100 g): > 75
- Glucose (% dry basis): ≤ 5.0
- Isomaltose + DP3 to DP9 (% dry basis): ≥ 90
- pH: 4 - 6
- Sulphated ash (g/100 g): ≤ 0.3

- Heavy metals:
  - Lead (mg/kg):  $\leq 0.5$
  - Arsenic (mg/kg):  $\leq 0.5$