



2025/97

22.1.2025

**COMMISSION IMPLEMENTING REGULATION (EU) 2025/97**

**of 21 January 2025**

**amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use and the specifications of the novel food isomalto-oligosaccharide**

**(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 <sup>(1)</sup>, and in particular Article 12(1) 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 <sup>(2)</sup> has established a Union list of novel foods.
- (3) The novel food isomalto-oligosaccharide was authorised under certain conditions of use by the UK competent authority <sup>(3)</sup>.
- (4) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 therefore includes isomalto-oligosaccharide as an authorised novel food.
- (5) On 26 March 2021, the company BioNeutra North America Inc. ('the applicant') submitted an application for the existing conditions of use, for extension of the conditions of use and new specifications for the novel food isomalto-oligosaccharide in accordance with Article 10(1) of Regulation (EU) 2015/2283. In addition to the existing authorised conditions of use the applicant requested for isomalto-oligosaccharide to be used in ice cream and other dairy desserts, instant coffee and tea, table-top sweeteners, cakes, muffins and pies, pastries, breakfast cereals, condiments/relishes, gravies and sauces, gelatines, puddings, fruit pie fillings, jams and jellies, yoghurts, milk based drinks, snack foods, sweet sauces, toppings and syrups, as well as in food supplements, as defined in Directive 2002/46/EC of the European Parliament and of the Council <sup>(4)</sup>, for the general population above 10 years of age.
- (6) The applicant asked for an authorisation of the existing authorised conditions of use. However, the Commission notes that those conditions of use are already authorised and are applicable to all food business operators, including the applicant therefore, this authorisation should be limited to the new conditions of use only.

<sup>(1)</sup> OJ L 327, 11.12.2015, p. 1, ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>.

<sup>(2)</sup> 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](http://data.europa.eu/eli/reg_impl/2017/2470/oj)).

<sup>(3)</sup> [https://food.ec.europa.eu/system/files/2016-11/novel-food\\_authorisation\\_2016\\_auth-letter\\_isomalto-oligosaccharide\\_en.pdf](https://food.ec.europa.eu/system/files/2016-11/novel-food_authorisation_2016_auth-letter_isomalto-oligosaccharide_en.pdf).

<sup>(4)</sup> 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>).

- (7) With regard to the conditions of use of the novel food in food supplements, the applicant initially proposed the maximum intake level of 30 g/day but subsequently agreed to reduce it to 10 g/day as the substance is a source of glucose. The applicant also proposed an additional condition of use that food supplements containing isomalto-oligosaccharide should not be consumed if other foods with added isomalto-oligosaccharide are consumed on the same day.
- (8) On 26 March 2021, the applicant also made a request to the Commission for the protection of proprietary scientific studies and data, namely, the compositional analyses data and an expert opinion on those data <sup>(3)</sup>, the product batch data <sup>(4)</sup>, the request of the applicant to the competent authorities of the United Kingdom in accordance with Article 4 of Regulation (EC) No 258/97 of the European Parliament and of the Council <sup>(7)</sup> to place isomalto-oligosaccharide on the market as a novel food ingredient <sup>(8)</sup>, the certificates of analyses <sup>(9)</sup>, the descriptions of the analytical methods <sup>(10)</sup>, the laboratory accreditation certificates <sup>(11)</sup>, the isomalto-oligosaccharide intake assessment reports <sup>(12)</sup>, a stability study <sup>(13)</sup>, a double-blind, randomised, placebo controlled study to investigate the effects of isomalto-oligosaccharide in healthy adults <sup>(14)</sup>, and a randomised, triple-blind placebo-controlled parallel study to evaluate the safety and tolerability of isomalto-oligosaccharide on a healthy adult population <sup>(15)</sup>, submitted in support of the application.
- (9) In accordance with Article 10(3) of Regulation (EU) 2015/2283, on 7 December 2021, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of the proposed new conditions of use and additional specifications for isomalto-oligosaccharide as a novel food.
- (10) On 14 December 2023, the Authority adopted its scientific opinion on the 'extension of use of isomalto-oligosaccharide as a novel food pursuant to Regulation (EU) 2015/2283' <sup>(16)</sup>, in accordance with Article 11 of Regulation (EU) 2015/2283.
- (11) In its scientific opinion, the Authority concluded that isomalto-oligosaccharide is safe under the proposed new conditions of use and for the proposed target populations. In its opinion, the Authority also considered that the proposed microbiological parameters should be added to the specifications of this novel food as a mean to reinforce its safety. It is therefore appropriate that the specifications of isomalto-oligosaccharide for the proposed new conditions of use include microbiological parameters.
- (12) The scientific opinion of the Authority gives sufficient grounds to establish that isomalto-oligosaccharide, when used under the new conditions of use fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283

---

<sup>(3)</sup> BioNeutra North America Inc., 2021, 2022, 2023 (unpublished).

<sup>(4)</sup> BioNeutra North America Inc., 2021 (unpublished).

<sup>(7)</sup> Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1, ELI: <http://data.europa.eu/eli/reg/1997/258/oj>).

<sup>(8)</sup> BioNeutra North America Inc., 2008 (unpublished).

<sup>(9)</sup> BioNeutra North America Inc., 2021 and 2022 (unpublished).

<sup>(10)</sup> BioNeutra North America Inc., 2021 (unpublished).

<sup>(11)</sup> BioNeutra North America Inc., 2021 (unpublished).

<sup>(12)</sup> BioNeutra North America Inc., 2021 (unpublished).

<sup>(13)</sup> BioNeutra North America Inc., 2022 (unpublished).

<sup>(14)</sup> BioNeutra North America Inc., 2012 (unpublished).

<sup>(15)</sup> BioNeutra North America Inc., 2020 (unpublished).

<sup>(16)</sup> EFSA Journal; 2024; 22:e8543, <https://doi.org/10.2903/j.efsa.2024.8543>.

- (13) In its scientific opinion, the Authority noted that its conclusion on the safety of the novel food under the new conditions of use and on the additional specifications was based on scientific studies and data, namely, the compositional analyses data and the expert opinion on those data; the product batch data, the request of the applicant to the competent authorities of the United Kingdom in accordance with Article 4 of Regulation (EC) No 258/97 to place isomalto-oligosaccharide on the market as a novel food ingredient, the certificates of analyses, the descriptions of the analytical methods, the laboratory accreditation certificates, the isomalto-oligosaccharide intake assessment reports, the stability study, the double-blind, randomised, placebo-controlled study to investigate the effects of isomalto-oligosaccharide in healthy adults, and the randomised, triple-blind, placebo-controlled, parallel study to evaluate the safety and tolerability of isomalto-oligosaccharide on a healthy adult population, contained in the applicant's file, without which it could not have assessed the novel food and reached its conclusion.
- (14) The Commission requested the applicant to further clarify the justification provided with regard to its proprietary claim over those scientific studies and data, and to clarify its claim to an exclusive right of reference to them in accordance with Article 26(2), point (b) of Regulation (EU) 2015/2283.
- (15) The applicant declared that, at the time of submission of the application, it held proprietary and exclusive rights of reference to the scientific studies and data, namely, the compositional analyses data and expert opinion on those data, the product batch data, the request of the applicant to the competent authorities of the United Kingdom in accordance with Article 4 of Regulation (EC) No 258/97 to place isomalto-oligosaccharide on the market as a novel food ingredient, the certificates of analyses, the descriptions of the analytical methods; the laboratory accreditation certificates, the isomalto-oligosaccharide intake assessment reports, the stability study, the double-blind, randomised, placebo-controlled study to investigate the effects of isomalto-oligosaccharide in healthy adults, and the randomised, triple-blind, placebo-controlled, parallel study to evaluate the safety and tolerability of isomalto-oligosaccharide on a healthy adult population, under national law and that third parties cannot lawfully access, use or refer to those data and studies.
- (16) 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 scientific studies and data submitted in support of the application, namely, the compositional analyses data and expert opinion on those data; the product batch data; the request of the applicant to the competent authorities of the United Kingdom in accordance with Article 4 of Regulation (EC) No 258/97 to place isomalto-oligosaccharide on the market as a novel food ingredient; the certificates of analyses; the descriptions of the analytical methods; the laboratory accreditation certificates; the isomalto-oligosaccharide intake assessment reports; the stability study; the double-blind, randomised, placebo controlled study to investigate the effects of isomalto-oligosaccharide in healthy adults; and the randomised, triple-blind, placebo-controlled, parallel study to evaluate the safety and tolerability of isomalto-oligosaccharide on a healthy adult population, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place its isomalto-oligosaccharide on the market within the Union during a period of 5 years from the entry into force of this Regulation.
- (17) However, restricting the authorisation of isomalto-oligosaccharide and the reference to the scientific studies and data contained in the applicant's file to the sole use by them does not prevent subsequent 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 an authorisation.
- (18) It is appropriate that the inclusion of isomalto-oligosaccharide produced by the applicant as a novel food in the Union list of novel foods contains also the information referred to in Article 9(3) of Regulation (EU) 2015/2283.

- (19) In line with the conditions of use of food supplements containing isomalto-oligosaccharide, it is necessary to inform consumers by appropriate labelling that food supplements containing isomalto-oligosaccharide should only be consumed by the general population over 10 years of age. It is also appropriate to inform the consumers that the novel food is a source of glucose. In addition, the Authority's opinion concluded that the cumulative intake of isomalto-oligosaccharide that would result from the already authorised uses and the proposed extended uses, including food supplements does not pose a safety concern. Taking into account the Authority's opinion, the Commission considers that requiring a label informing consumers that food supplements containing isomalto-oligosaccharide should not be used if other foods with added isomalto-oligosaccharide are consumed on the same day, as proposed by the applicant, is not necessary.
- (20) The applicant has proposed the use of isomalto-oligosaccharide in jams and jellies. Council Directive 2001/113/EC <sup>(17)</sup> defines products relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption. This Directive lays down specific provisions regarding the designation and compositional requirements of the products within its scope. Only certain designations relating to fruit jams, jellies and marmalades and sweetened chestnut purée and only certain ingredients and substances authorised by this Directive may be used. While the Union list of novel foods applies without prejudice to other provisions laid down in sector specific legislation, to ensure clarity and regulatory consistency, it is appropriate that the conditions of use of this novel food should reflect the restrictions imposed by the provisions of Directive 2001/113/EC.
- (21) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (22) 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*

Only the company BioNeutra North America Inc. <sup>(18)</sup> is authorised to place on the market within the Union isomalto-oligosaccharide as specified in the Annex, for a period of 5 years from the date of entry into force of this Regulation, 11 February 2025, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of BioNeutra North America Inc.

#### *Article 3*

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation, without the agreement of BioNeutra North America Inc.

<sup>(17)</sup> Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption (OJ L 10, 12.1.2002, p. 67, ELI: <http://data.europa.eu/eli/dir/2001/113/oj>).

<sup>(18)</sup> Address: 9608 25 Avenue NW, Edmonton, Alberta T6N 1J4, Canada.

*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, 21 January 2025.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------------|--------------------------------------------------------------------------------------------------------------------------------|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Isomalto-oligosaccharide | Specified food category                                                                                                        | Maximum levels | <div>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be “isomalto-oligosaccharide”.</div> <div>2. The designation of the novel food on the labelling shall be accompanied by indication that the isomalto-oligosaccharide is a source of glucose.</div> <div>3. The labelling of food supplements containing isomalto-oligosaccharide shall bear a statement that they should not be consumed by children under 10 years of age.</div> |                    | <div>Authorised on 11 February 2025. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</div> <div>Applicant: BioNeutra North America Inc., 9608 25 Avenue NW, Edmonton, Alberta T6N 1J4, Canada. During the period of data protection, the novel food isomalto-oligosaccharide is authorised for placing on the market within the Union only by BioNeutra North America Inc., 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 BioNeutra North America Inc.</div> <div>End date of the data protection: 11 February 2030.’</div> |
|                          | Ice cream, dairy desserts                                                                                                      | 8 %            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                          | Instant coffee and tea                                                                                                         | 10 %           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                          | Table-top sweeteners                                                                                                           | 100 %          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                          | Cakes, muffins and pies                                                                                                        | 20 %           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                          | Pastries                                                                                                                       | 15 %           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                          | Breakfast cereals                                                                                                              | 10 %           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                          | Savoury sauces, gravies and condiments                                                                                         | 10 %           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                          | Gelatines and puddings                                                                                                         | 15 %           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                          | Fruit pie fillings                                                                                                             | 15 %           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                          | Fruit spreads (except products defined in Part I of Annex I to Directive 2001/113/EC)                                          | 50 %           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                          | Yoghurts                                                                                                                       | 2,5 %          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                          | Milk-based drinks                                                                                                              | 5 %            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                          | Cereal-, fruit- or vegetable-based snacks                                                                                      | 5 %            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                          | Sweet sauces, toppings and syrups                                                                                              | 50 %           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                          | Food supplements as defined in Directive 2002/46/EC, for the general population, excluding children, under the age of 10 years | 10 g/day       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

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

| Authorised novel food    | Specification                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Isomalto-oligosaccharide | <b>Powder</b><br>Solubility (water) (%): > 99,0<br>Glucose (% dry basis): ≤ 5,0<br>Isomaltose + DP3 to DP9 (% dry basis): ≥ 90,0<br>Moisture (%): ≤ 4,0<br>Sulphated ash (g/100 g): ≤ 0,3<br><b>Heavy metals:</b><br>Lead (mg/kg): ≤ 0,5<br>Arsenic (mg/kg): ≤ 0,5<br><b>Microbiological criteria:</b><br>Total Aerobic Microbial Count: ≤ 1 000 CFU/g<br>Yeasts and moulds: ≤ 100 CFU/g<br><i>Escherichia coli</i> : Absence in 10 g<br><i>Salmonella</i> spp.: Absence in 25 g                  |
|                          | <b>Syrup</b><br>Dried solids (g/100 g): > 75<br>Glucose (% dry basis): ≤ 5,0<br>Isomaltose + DP3 to DP9 (% dry basis): ≥ 90<br>pH: 4–6<br>Sulphated ash (g/100 g): ≤ 0,3<br><b>Heavy metals:</b><br>Lead (mg/kg): ≤ 0,5<br>Arsenic (mg/kg): ≤ 0,5<br><b>Microbiological criteria:</b><br>Total Aerobic Microbial Count: ≤ 1 000 CFU/g<br>Yeasts and moulds: ≤ 100 CFU/g<br><i>Escherichia coli</i> : Absence in 10 g<br><i>Salmonella</i> spp.: Absence in 25 g<br><br>CFU: colony forming units' |