COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

authorising the placing on the market of isomalto-oligosachharide as a novel food and amending 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(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[2] has established a Union list of novel foods.

(3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes isomalto-oligosaccharide as an authorised novel food.

(4) On 26 March 2021, the company BioNeutra North America Inc. ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place its isomalto-oligosaccharide on the Union market as a novel food. The applicant requested for the isomalto-oligosaccharide to be used in the same food categories and at the same maximum levels as the currently authorised isomalto-oligosaccharide and, in addition, in ice cream and dairy desserts, instant coffee and tea, table-top sweeteners, cakes and pastries, breakfast cereals, savoury sauces, pickles, gravies and condiments, jams and jellies, gelatines, puddings and fillings, yoghurts, milk-based drinks and similar products, snacks, sauces, toppings and syrups, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[3] intended for the general population above 10 years of age. With regard to conditions of use, the applicant also proposed that food supplements containing isomalto-oligosaccharide

---

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

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), ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj.

3 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).

should not be consumed if other foods with added isomalto-oligosaccharide are consumed on the same day.

(5) 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 expert opinion on these data[4]; the product batch data[5], the request of the applicant to the competent authorities of the United Kingdom in accordance with Article 4 of Regulation (EC) 258/97 of the European Parliament and of the Council[6] to place isomalto-oligosaccharide on the market as a novel food ingredient[7]; the certificates of analyses[8]; the descriptions of the analytical methods[9], the laboratory accreditation certificates[10]; the isomalto-oligosaccharide intake assessment reports[11], the stability study[12]; a double-blind, randomised, placebo controlled study to investigate the effects of isomalto-oligosaccharide in healthy adults[13]; and a randomised, triple-blind, placebo-controlled, parallel study to evaluate the safety and tolerability of isomalto-oligosaccharide on a healthy adult population[14], submitted in support of the application.

(6) 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 isomalto-oligosaccharide as a novel food.

(7) 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'[15], in accordance with Article 11 of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority concluded that isomalto-oligosaccharide is safe under the proposed conditions of use and for the proposed target populations. Therefore, that scientific opinion gives sufficient grounds to establish that isomalto-oligosaccharide when used in the same food categories and at the same maximum levels as the currently authorised isomalto-oligosaccharide, and when used in ice cream and dairy desserts, instant coffee and tea, table-top sweeteners, cakes and pastries, breakfast cereals, savoury sauces, pickles, gravies and condiments, jams and jellies, gelatines, puddings and fillings, yoghurts, milk-based drinks and similar products, snacks, sauces, toppings and syrups, and in food supplements as defined in Directive 2002/46/EC intended for the general population above 10 years of age, complies with the authorisation requirements laid down Article 12(1) of Regulation (EU) 2015/2283.

(9) In its scientific opinion, the Authority noted that its conclusion on the safety of the novel food was based on scientific studies and data from the compositional analyses

4 BioNeutra North America Inc. 2021, 2022, 2023 (unpublished).
5 BioNeutra North America Inc. 2021 (unpublished).
6 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.
7 BioNeutra North America Inc. 2008 (unpublished).
8 BioNeutra North America Inc. 2021 and 2022 (unpublished).
9 BioNeutra North America Inc. 2021 (unpublished).
10 BioNeutra North America Inc. 2021 (unpublished).
11 BioNeutra North America Inc. 2021 (unpublished).
12 BioNeutra North America Inc. 2022 (unpublished).
13 BioNeutra North America Inc. 2012 (unpublished).
14 BioNeutra North America Inc. 2020 (unpublished).
15 EFSA Journal. 2024;22:e8543. https://doi.org/10.2903/j.efsa.2024.8543.

data and expert opinion on these 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) 258/97 of the European Parliament and of the Council 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.

(10) 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.

(11) 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 these 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) 258/97 of the European Parliament and of the Council 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.

(12) 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 these 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) 258/97 of the European Parliament and of the Council 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 five years from the entry into force of this Regulation.

(13) However, restricting the authorisation of the applicant's isomalto-oligosaccharide and the reference to the scientific studies and data contained in the applicant's file for 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.

(14) In line with the conditions of use of food supplements isomalto-oligosaccharide, as proposed by the applicant, it is necessary to inform consumers by appropriate labelling that food supplements containing isomalto-oligosaccharide, should not be consumed by infants and children under ten years of age and should not be used if other foods with added isomalto-oligosaccharide are consumed on the same day.

(15) 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.

(16) Isomalto-oligosaccharide produced by the applicant should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(17) 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. Isomalto-oligosaccharide produced by the company BioNeutra North America Inc. is authorised to be placed on the market within the Union.

2. Isomalto-oligosaccharide produced by the company BioNeutra North America Inc. shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

   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.[16] is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of 5 years from the date of entry into force of this Regulation [*OP please insert the date of entry into force of this Regulation*], 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.., Ltd.

[16] 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,

For the Commission
The President
Ursula VON DER LEYEN