Commission Implementing Regulation (EU) 2020/916 of 1 July 2020 authorising the extension of use of xylo-oligosaccharides 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/916

of 1 July 2020

authorising the extension of use of xylo-oligosaccharides 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 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) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to submit a draft implementing act authorising placing on the Union market of a novel food and on the updating of the Union list.

(4) Commission Implementing Regulation (EU) 2018/1648[(3)] authorised the placing on the Union market of xylo-oligosaccharides as a novel food under Regulation (EU) 2015/2283, to be used in a number of food categories, namely, bread, breakfast cereals, biscuits, soy-drinks, yoghurt, fruit spreads and chocolate confectionery for the general population.

(5) On 25 November 2019, the company Shandong Longlive Biotechnology Co. Ltd submitted an application to the Commission to change the conditions of use of the novel xylo-oligosaccharides pursuant to Article 10(1) of Regulation (EU) 2015/2283. The application requested to extend the use of xylo-oligosaccharides in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[(4)] intended for the general adult population at the maximum use levels of 2 g per day.

(6) The Commission considers that a safety evaluation of the current application by the European Food Safety Authority ('the Authority') in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary, as the proposed extension of use of xylo-oligosaccharides is covered by the safety assessment conducted by the Authority[(5)] underlying the authorisation of xylo-oligosaccharides by Implementing Regulation (EU) 2018/1648.

(7) In that opinion, the Authority conducted a conservative exposure assessment, using the highest anticipated daily intake based on the assumption that a person would consume all proposed food products containing the maximum added amount of the xylo-oligosaccharides. On the basis of this exposure assessment, the Authority concluded that the resulting highest anticipated daily intake of 7,7 g of xylo-oligosaccharides per day still remains way below both, the daily intake levels of 10–12 g of xylo-oligosaccharides that were associated with acute and transient gastro-intestinal effects in human clinical intervention studies, and below the Dietary Reference Value ('DRV') of 25 g of dietary fibre per day for the general adult population previously established by the Authority[(6)].

(8) The intake from the proposed extension of use of xylo-oligosaccharides in food supplements at levels of 2 g per day, combined with the highest intake of 7,7 g xylo-oligosaccharides from its currently authorised uses as a novel food, could result in an overall maximum intake of 9,7 g xylo-oligosaccharides per day. This overall intake level will also be below both the intake levels of 10–12 g of xylo-oligosaccharides that were associated with acute and transient gastro-intestinal effects in human clinical intervention studies, and below the Dietary Reference Value ('DRV') of 25 g dietary fibre per day for the general adult population established by the Authority.

(9) The information provided in the application and the scientific opinion of the Authority combined with the above considerations give sufficient grounds to establish that the proposed extension of use of the novel food 'xylo-oligosaccharides' complies with Article 12 of Regulation (EU) 2015/2283.

(10) It is therefore appropriate to amend the conditions of use of xylo-oligosaccharides in the Union list of authorised novel foods by including the use of xylo-oligosaccharides in food supplements intended for the adult population.

(11) 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 Union list of authorised novel foods, established under Implementing Regulation (EU) 2017/2470, referring to the novel food xylo-oligosaccharides, is amended as specified in the Annex to this Regulation.

Article 2

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 3

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, 1 July 2020.

For the Commission

The President

Ursula VON DER LEYEN