Commission Implementing Regulation (EU) 2018/1648 of 29 October 2018 authorising the placing on the market 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) 2018/1648

of 29 October 2018

authorising the placing on the market 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 of the European Parliament and of the Council 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 decide on the authorisation and on the placing on the Union market of a novel food and on the updating of the Union list.

(4) On 4 May 2016, the company Longlive Europe Food Division Ltd ('the Applicant') submitted a request to the competent authority of Hungary to place xylo-oligosaccharides on the Union market as a novel food ingredient within the meaning of point (e) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council[(3)]. The application requests for xylo-oligosaccharides to be used in a number of food categories, namely, bakery and dairy products, fruit spreads, chocolate confectionery and soy-drinks for the general population.

(5) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, and for which the final decision has not

been taken before 1 January 2018, shall be treated as an application submitted under Regulation (EU) 2015/2283.

(6) While the request for placing xylo-oligosaccharides on the market as a novel food within the Union was submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.

(7) On 18 July 2016, the competent authority of Hungary issued its initial assessment report. In that report, it concluded that xylo-oligosaccharides meets the criteria for a novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.

(8) On 12 June 2017, the Commission forwarded the initial assessment report to the other Member States. Reasoned objections were raised by other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97 with regard to the specifications, stability, anticipated daily intake and toxicological studies.

(9) In view of the objections raised by the other Member States, the Commission consulted the European Food Safety Authority ('the Authority') on 6 September 2017, asking it to carry out an additional assessment for xylo-oligosaccharides as a novel food ingredient in accordance with Regulation (EC) No 258/97.

(10) On 27 June 2018, the Authority adopted the 'Scientific Opinion on the safety of xylo-oligosaccharides as a novel food pursuant to Regulation (EU) 2015/2283'[(4)]. This opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(11) That opinion gives sufficient grounds to establish that xylo-oligosaccharides in the proposed uses and use levels when used as an ingredient in bakery and dairy products, fruit spreads, chocolates and soy-drinks, complies with Article 12(1) of Regulation (EU) 2015/2283.

(12) Regulation (EU) No 1308/2013 of the European Parliament and of the Council[(5)] lays down requirements for milk and milk products which apply to xylo-oligosaccharides when used as an ingredient in milk products. Pursuant to point 2 of Part III of Annex VII to that Regulation, xylo-oligosaccharides cannot be used in milk products to replace, in whole or in part, any milk constituent. The use of xylo-oligosaccharides as a novel food in milk products should therefore be limited accordingly.

(13) 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 Xylo-oligosaccharides as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2 The entry in the Union list referred to in the first paragraph shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

3 The authorisation provided for in this Article shall be without prejudice to the provisions of Regulation (EU) No 1308/2013.

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, 29 October 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1648. (See end of Document for details)*

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) The following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

Authorised novel food	**Conditions under which the novel food may be used**		**Additional specific labelling requirements**	**Other requirements**
'Xylo-oligosaccharides	***Specified food category***	***Maximum levels* (**)**	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Xylo-oligosaccharides"'	
	White bread	14 g/kg		
	Whole meal bread	14 g/kg		
	Breakfast cereals	14 g/kg		
	Biscuits	14 g/kg		
	Soy drink	3,5 g/kg		
	Yoghurt (*)	3,5 g/kg		
	Fruit spreads	30 g/kg		
	Chocolate confectionery	30 g/kg		
	(*) When used in milk products xylo-oligosaccharides shall not replace, in whole or in part, any milk constituent (**) Maximum levels calculated on the basis of the specifications of Powder form 1.			

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

Authorised Novel Food	**Specification**			
'Xylo-oligosaccharides	**Description:** The novel food is a mixture of xylo-oligosaccharides (XOS) which are obtained from corncobs (*Zea mays* subsp. *mays*) via hydrolysis by a xylanase from *Trichoderma reesei* followed by a purification process. **Characteristics/Composition**			
	Parameter	**Powder form 1**	**Powder form 2**	**Syrup form**
	Moisture (%)	≤ 5,0	≤ 5,0	70-75