

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

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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.

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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

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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	<p>Description: The novel food is a mixture of xylo-oligosaccharides (XOS) which are obtained from corncobs (<i>Zea mays</i> subsp. <i>mays</i>) via hydrolysis by a xylanase from <i>Trichoderma reesei</i> followed by a purification process.</p> <p>Characteristics/Composition</p>

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Parameter	Powder form 1	Powder form 2	Syrup form
Moisture (%)	≤ 5,0	≤ 5,0	70-75
Protein (g/100 g)	< 0,2		
Ash (%)	≤ 0,3		
pH	3,5-5,0		
Total carbohydrate content (g/100 g)	≥ 97	≥ 95	≥ 70
XOS content (dry basis) (g/100 g)	≥ 95	≥ 70	≥ 70
Other carbohydrates (g/100 g) ^(a)	2,5-7,5	2-16	1,5-31,5
Monosaccharides total (g/100 g)	0-4,5	0-13	0-29
Glucose (g/100 g)	0-2	0-5	0-4
Arabinose (g/100 g)	0-1,5	0-3	0-10
Xylose (g/100 g)	0-1,0	0-5	0-15
Disaccharides total (g/100 g)	27,5-48	25-43	26,5-42,5
Xylobiose (XOS DP2) (g/100 g)	25-45	23-40	25-40
Cellobiose (g/100 g)	2,5-3	2-3	1,5-2,5
Oligosaccharides total (g/100 g)	41-77	36-72	32-71
xylotriose (XOS DP3) (g/100 g)	27-35	18-30	18-30
xylotetraose (XOS DP4) (g/100 g)	10-20	10-20	8-20
xylopentaose (XOS DP5) (g/100 g)	3-10	5-10	3-10

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xylohexaose (XOS DP6) (g/100 g)	1-5	1-5	1-5
Xyloheptaose (XOS DP7) (g/100 g)	0-7	2-7	2-6
Maltodextrin (g/100 g) ^(b)	0	20-25	0
Copper (mg/kg)	< 5,0		
Lead (mg/kg)	< 0,5		
Arsenic (mg/kg)	< 0,3		
<i>Salmonella</i> (CFU ^(c) /25 g)	Negative		
<i>E. coli</i> (MPN ^(d) /100 g)	Negative		
Yeast (CFU/g)	< 10		
Mould (CFU/g)	< 10		
DP	: Degree of polymerization		
^(a)	Other carbohydrates include monosaccharides (glucose, xylose and arabinose) and cellobiose.		
^(b)	Maltodextrin content is calculated according to the amount added in the process.		
^(c)	CFU: Colony Forming Units.		
^(d)	MPN: Most Probable Number.†		

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- (1) [OJ L 327, 11.12.2015, p. 1.](#)
- (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.](#))
- (3) 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.](#))
- (4) EFSA Journal 2018;16(7): 5361
- (5) Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([OJ L 347, 20.12.2013, p. 671.](#))

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