

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

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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:

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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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