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## **COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of XXX**

### **authorising an 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<sup>1</sup>, 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<sup>2</sup> 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<sup>3</sup> authorised, in accordance with Regulation (EC) No 258/97, the placing on the market in the Union of xylo-oligosaccharides as a novel food 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 a request to the Commission to change the conditions of use of the novel xylo-oligosaccharides within the meaning of Article 10(1) of Regulation (EU)

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<sup>1</sup> OJ L 327, 11.12.2015, p. 1.

<sup>2</sup> 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).

<sup>3</sup> 2009/827/EC: Commission Decision of 13 October 2009 authorising the placing on the market of Chia seed (*Salvia hispanica*) as novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 294, 11.11.2009, p. 14).

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2015/2283. The application requested to extend the use of xylo-oligosaccharides in ~~additional food category, namely, food~~ supplements intended for the general population, excluding food supplements for infants and children under 2 years of age.

~~(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 -~~

~~(7)~~(6) ~~The~~ proposed extension of use of xylo-oligosaccharides does not alter the conclusions of the safety assessment conducted by the Authority<sup>4</sup> that supported its authorisation by Commission Implementing Regulation (EU) 2018/1648.

~~(8)~~(7) The information provided in the application and the Authority's scientific opinion gives sufficient grounds to establish that the proposed extension of use of the novel food 'xylo-oligosaccharides' comply with Article 12 of Regulation (EU) 2015/2283.

~~(9)~~(8) It is therefore appropriate that the conditions of xylo-oligosaccharides as listed in the Union list of authorised novel foods are amended by including the above food category.

~~(10)~~(9) Directive 2002/46/EC of the European Parliament and of the Council<sup>5</sup> lays down requirements on food supplements. The extension of use of xylo-oligosaccharides should be authorised without prejudice to the requirements of that Directive.

~~(11)~~(10) 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. The Union list of authorised novel foods, as provided for in Article 6 of Regulation (EU) 2015/2283 and included in Implementing Regulation (EU) 2017/2470, referring to the novel food xylo-oligosaccharides, is amended as specified in the Annex to this Regulation.

2. The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC.

#### *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*.

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<sup>4</sup> Scientific Opinion on the safety of xylo-oligosaccharides as a novel food pursuant to Regulation (EU) 2015/2283 (EFSA Journal 2018;16(7): 5361).

<sup>5</sup> 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).

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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*