COMMISSION IMPLEMENTING REGULATION (EU) 2018/462

of 20 March 2018

authorising an extension of use of L-ergothioneine 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]) was adopted, which establishes a Union list of authorised novel foods.

(3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission shall submit a draft implementing act on the placing on the Union market of a novel food and on the updating of the Union list.

(4) On 25 July 2013, the company Tetrahedron made a request to the competent authority of France to place synthetic L-ergothioneine ('L-ergothioneine') on the Union market as a novel food ingredient within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97 ([3]). The application requested for L-ergothioneine to be used in food supplements for the general population excluding pregnant and lactating women and for children older than three years, and in non-alcoholic beverages, fresh milk products, milk based drinks, cereal bars and chocolate for the general population excluding pregnant and lactating women, infants and young children.

(5) On 26 October 2016, EFSA adopted a 'Scientific Opinion on the safety of L-ergothioneine as a novel food pursuant to Regulation (EC) No 258/97' ([4]). In its opinion it concluded that L-ergothioneine is safe for the proposed uses and use levels.

(6) Commission Implementing Decision (EU) 2017/1281 ([5]) authorised, in accordance with Regulation (EC) No 258/97, the placing on the market of L-ergothioneine as a novel food ingredient to be used in food supplements intended for the general population, excluding infants and young children, pregnant and lactating women.

(7) This Implementing Regulation addresses the remainder of the uses and use levels for which authorisation was sought by the applicant. The Commission initiated a further evaluation before taking a final decision on the full scope of the application, in order to ensure that L-ergothioneine is also safe when consumed in other forms than in food supplements by infants, young children, pregnant and lactating women.

(8) On 26 April 2017, the applicant was informed of and agreed with the Commission's additional request to EFSA.

([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* 2016; 14(11):4629
([5]) Commission Implementing Decision (EU) 2017/1281 of 13 July 2017 authorising the placing on the market of L-ergothioneine as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 184, 15.7.2017, p. 65).

(9) On 19 May 2017, the Commission consulted EFSA asking it to carry out a supplementary safety assessment for L-ergothioneine in non-alcoholic beverages, fresh milk products, milk-based drinks, cereal bars and chocolate for pregnant and lactating women, infants and young children.

(10) 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 concerning novel foods and novel food ingredients 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.

(11) On 25 October 2017, EFSA adopted a 'Scientific Opinion on the safety of L-ergothioneine' [1]. This opinion, although elaborated and adopted by EFSA under Regulation (EC) No 258/97 is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(12) The opinion gives sufficient grounds to establish that L-ergothioneine when used as an ingredient in non-alcoholic beverages, fresh milk products, milk-based drinks, cereal bars and chocolate confectionery taking into account all population groups, complies with Article 12(1) of Regulation (EU) 2015/2283.

(13) Regulation (EU) No 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products [2] lays down requirements for milk and milk products which apply to L-ergothioneine when used as an ingredient in milk products. Pursuant to its point 2 of Part III of Annex VII L-ergothioneine cannot be used in milk products to replace, in whole or in part, any milk constituent. The use of L-ergothioneine as a novel food in milk products therefore has to be limited accordingly.

(14) 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 entry in the Union list of authorised novel foods as provided for in Article 8 of Regulation (EU) 2015/2283 referring to the substance L-ergothioneine shall be amended as specified in the Annex to this Regulation

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.

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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[1] EFSA Journal 2017; 15(11):5060.

[2] 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).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 March 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

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

The entry for 'L-ergothioneine' in Table 1 (Authorised novel foods) is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'L-ergothioneine	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be "L-ergothioneine"'	
	Alcohol-free beverages	0,025 g/kg		
	Milk-based drinks	0,025 g/kg		
	'Fresh' milk products (*)	0,040 g/kg		
	Cereal bars	0,2 g/kg		
	Chocolate confectionery	0,25 g/kg		
	Food supplements as defined in Directive 2002/46/EC	30 mg/day for general population (excluding pregnant and lactating women) 20 mg/day for children older than 3 years		
	(*) When used in milk products L-ergothioneine may not replace in whole or in part, any milk constituent			