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

(notified under document C(2017) 4844)

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [(1)], and in particular Article 7 thereof,

Whereas:

(1) On 25 July 2013, the company Tetrahedron made a request to the competent authorities 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. The application excluded from the use infants, young children, pregnant and lactating women.

(2) On 19 February 2015, the competent food assessment body of France issued its initial assessment report. In that report it came to the conclusion that L-ergothioneine meets the criteria for novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.

(3) On 9 March 2015, the Commission forwarded the initial assessment report to the other Member States.

(4) 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.

(5) On 14 October 2015, the Commission consulted the European Food Safety Authority ('EFSA') asking it to carry out an additional assessment for L-ergothioneine as novel food ingredient in accordance with Regulation (EC) No 258/97.

(6) On 26 October 2016, EFSA in its 'Scientific Opinion on the safety of L-ergothioneine as a novel food pursuant to Regulation (EC) No

258/97’ [2] concluded that L-ergothioneine is safe for the proposed uses and use levels.

(7) That opinion gives sufficient grounds to establish that L-ergothioneine in the proposed uses and use levels complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(8) Directive 2002/46/EC of the European Parliament and of the Council [3] lays down requirements on food supplements. The use of L-ergothioneine should be authorised without prejudice to the provisions of that Directive.

(9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Without prejudice to Directive 2002/46/EC, L-ergothioneine as specified in Annex I may be placed on the Union market as a novel food ingredient to be used in food supplements intended for the general population, excluding infants and young children, and pregnant and lactating women, for the uses defined and at the maximum levels established in Annex II.

Article 2

The designation of L-ergothioneine authorised by this Decision on the labelling of the foodstuffs shall be ‘L-ergothioneine’.

Article 3

This Decision is addressed to Tetrahedron, 14, avenue de l'Opéra, 75001 Paris, France.

Done at Brussels, 13 July 2017.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

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[1] OJ L 43, 14.2.1997, p. 1.

[2] *EFSA Journal* 2016;14(11):4629.

[3] 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).

ANNEX I

SPECIFICATIONS OF L-ERGOTHIONEINE

Definition

Chemical name (IUPAC)	(2S)-3-(2-thioxo-2,3-dihydro-1*H*-imidazol-4-yl)-2-(trimethylammonio)-propanoate
Chemical formula	$C_9H_{15}N_3O_2S$
Molecular mass	229,3 Da
CAS No	497-30-3
IUPAC: International Union for Pure and Applied Chemistry	

Specifications

Parameter	Specification	Method
Appearance	White powder	Visual
Optical rotation	$[\alpha]_D$ ⩾ (+) 122° (c = 1, H_2O) (1)	Polarimetry
Chemical purity	⩾ 99,5 %	HPLC [Eur. Ph. 2.2.29]
	⩾ 99 %	1H-NMR
Identification	Compliant with the structure	1H-NMR
	C: 47,14 ± 0,4 %	
	H: 6,59 ± 0,4 %	
	N: 18,32 ± 0,4 %	Elemental analysis
Total residual solvents (methanol, ethyl acetate, isopropanol, ethanol)	[Eur. Ph. 01/2008:50400] < 1 000 ppm	Gas chromatography [Eur. Ph. 01/2008:20424]

Loss on drying	Internal standard < 0,5 %	[Eur. Ph. 01/2008:20232]
Impurities	< 0,8 %	HPLC/GPC or 1H-NMR
Heavy metals (2) (3)		
Lead	< 3 ppm	ICP/AES (Pb, Cd) Atomic fluorescence (Hg)
Cadmium	< 1 ppm	
Mercury	< 0.1 ppm	
Microbiological specifications (2)		
Total viable aerobic count (TVAC)	⩽ 1 × 10^3 CFU/g	[Eur. Ph. 01/2011:50104]
Total yeast and mould count (TYMC)	⩽ 1 × 10^2 CFU/g	
Escherichia coli	Absent in 1 g	

Eur. Ph.: European Pharmacopoeia; 1H-NMR: proton nuclear magnetic resonance; HPLC: high-performance liquid chromatography; GPC: gel permeation chromatography; ICP/AES: Inductively coupled plasma atomic emission spectroscopy;

CFU: colony-forming units.

(1) Lit. $[\alpha]_D$ = (+) 126,6° (c = 1, H_20)

(2) Analyses conducted on each batch

(3) Maximum levels in accordance with Commission Regulation (EC) No 1881/2006 (OJ L 364, 20.12.2006, p. 5).

ANNEX II

AUTHORISED USES OF L-ERGOTHIONEINE

Food category	Maximum levels
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