

COMMISSION IMPLEMENTING DECISION (EU) 2017/2373**of 14 December 2017****authorising the placing on the market of hydroxytyrosol as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council***(notified under document number C(2017) 8423)***(Only the Spanish 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 12 June 2014, the company Seprox Biotech made a request to the competent authority of Spain to place synthetic hydroxytyrosol ('hydroxytyrosol') 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 target population is the general population excluding children under the age of three years, pregnant women, and lactating women.
- (2) On 2 March 2015, the competent authority of Spain issued its initial assessment report. In that report it came to the conclusion that hydroxytyrosol meets the criteria for novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.
- (3) On 10 April 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 19 November 2015, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment for hydroxytyrosol as novel food ingredient in accordance with Regulation (EC) No 258/97.
- (6) On 31 January 2017, EFSA in its 'Scientific Opinion on the safety of hydroxytyrosol as a novel food pursuant to Regulation (EC) No 258/97' ⁽²⁾ concluded that hydroxytyrosol is safe for the proposed uses and use levels.
- (7) That opinion gives sufficient grounds to establish that hydroxytyrosol in the proposed uses and use levels complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
- (8) Taking into account that the request for authorisation excludes certain groups of population and imposes certain conditions for the technical performance of foods containing hydroxytyrosol when heated, food products containing hydroxytyrosol should be appropriately labelled.
- (9) Regulation (EC) No 1925/2006 of the European Parliament and of the Council ⁽³⁾ lays down requirements on the addition of vitamins and minerals and of certain other substances to foods. The use of hydroxytyrosol should be authorised without prejudice to that Regulation.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.⁽²⁾ EFSA Journal 2017;15(3):4728.⁽³⁾ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

HAS ADOPTED THIS DECISION:

Article 1

Without prejudice to Regulation (EC) No 1925/2006, hydroxytyrosol as specified in Annex I to this Decision may be placed on the Union market as a novel food ingredient intended for the general population, excluding children under the age of three years, pregnant women, and lactating women, for the uses defined and at the maximum levels established in Annex II to this Decision.

Article 2

1. The designation of hydroxytyrosol authorised by this Decision for the labelling of the food products shall be 'hydroxytyrosol'.
2. The labelling of the food products containing hydroxytyrosol shall bear the following statements:
 - (a) 'This food product should not be consumed by children under the age of three years, pregnant women, and lactating women;
 - (b) This food product should not be used for cooking, baking or frying'.

Article 3

This Decision is addressed to Seprox Biotech, Centro Empresarial Ingenia N-8, Parque Tecnológico Fuente Álamo, 30320 Fuente Álamo, Murcia, Spain.

Done at Brussels, 14 December 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX I

SPECIFICATIONS OF HYDROXYTYROSOL

Definition:

Chemical name	IUPAC name: 4-(2-hydroxyethyl)-benzene-1,2-diol Synonyms: 3-Hydroxytyrosol 3,4-dihydroxyphenylethanol Dihydroxyphenylethanol 2-(3,4-Di-hydroxyphenyl)-ethanol
Chemical formula	C ₈ H ₁₀ O ₃
Molecular mass	154,16 Da
CAS No.	10597-60-1

Description: Hydroxytyrosol is a pale-yellow viscous liquid.

Specifications:

Parameter	Specifications
Description	Slightly yellow viscous liquid
Moisture	≤ 4,0 %
Odour	Characteristic
Taste	Slightly bitter
Solubility (water)	Miscible with water
pH	3,5-4,5
Refractive Index (25 °C)	1,571-1,575
Hydroxytyrosol and organic by-products of the chemical synthesis	
Hydroxytyrosol	≥ 99,0 %
Acetic acid	≤ 0,4 %
Hydroxytyrosol acetate	≤ 0,3 %
Sum of homovanillic alcohol, iso-homovanillic alcohol, and 3-methoxy-4-hydroxyphenylglycol	≤ 0,3 %
Heavy Metals	
Lead	≤ 0,03 mg/kg
Cadmium	≤ 0,01 mg/kg
Mercury	≤ 0,01 mg/kg
Residual solvents	
Ethyl acetate	≤ 25,0 mg/kg
Isopropanol	≤ 2,50 mg/kg
Methanol	≤ 2,00 mg/kg
Tetrahydrofuran	≤ 0,01 mg/kg

ANNEX II

Authorised uses of hydroxytyrosol

Food category	Maximum level
Fish and vegetable oils, (except olive oils and olive pomace oils as defined in Part VIII of Annex VII of Regulation (EU) No 1308/2013 ⁽¹⁾), placed as such on the market	0,215 g/kg
Spreadable fats as defined in Part VII of Annex VII of Regulation (EU) No 1308/2013, placed as such on the market	0,175 g/kg

⁽¹⁾ 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 Regulation (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) 1234/2007 (OJ L 347, 20.12.2013, p. 671).