COMMISSION IMPLEMENTING REGULATION (EU) 2022/672

of 22 April 2022

amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food *trans*-resveratrol (from microbial source)

(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 of novel foods 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]) has established a Union list of novel foods.

(3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes trans-resveratrol from synthetic and microbial sources as an authorised novel food.

(4) The novel food trans-resveratrol from a microbial source has been authorised as a novel food ingredient under pursuant to Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council ([3]) to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([4]), in capsule or tablet form, for the adult population on the basis of its substantial equivalence to resveratrol with a history of consumption before 15 May 1997 extracted from the Japanese knotweed (*Fallopia japonica*).

(5) Commission Implementing Decision (EU) 2016/1190 ([5]) authorised the placing on the Union market of synthetic trans-resveratrol as a novel food ingredient under Regulation (EC) No 258/97, also to be used in food supplements as defined in Directive 2002/46/EC in capsule or tablet form, for the adult population.

(6) Commission Implementing Regulation (EU) 2021/51 ([6]) amended the conditions of use of trans-resveratrol. In particular, the restrictions on the delivery formats of food supplements containing the novel food have been lifted.

([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]) 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).

([5]) Commission Implementing Decision (EU) 2016/1190 of 19 July 2016 authorising the placing on the market of *trans*-resveratrol as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 196, 21.7.2016, p. 53).

([6]) Commission Implementing Regulation (EU) 2021/51 of 22 January 2021 authorising a change of the conditions of use of the novel food 'trans-resveratrol' under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ, L 23, 25.1.2021, p. 10).

(7) On 29 July 2021, the company Evolva AG ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change of the specifications of trans-resveratrol from a microbial source. The applicant requested to remove the requirement that 100 % of the particles of the novel food produced by *S. cerevisiae* should be of a size less than 62,23 micrometres (< 62,23 μm).

(8) The applicant justifies the request by indicating that the change is necessary in order to take account of the variation in the particle sizes of trans-resveratrol from a microbial source in the course of its production process and processing for use in food supplements. In support of the request, the applicant provided analytical data demonstrating that the particle size profile of trans-resveratrol from a microbial source is comparable to the particle size profile of the chemically synthesised trans-resveratrol that was evaluated by the European Food Safety Authority ('the Authority') ([7]), and for which no particle size requirements are included in the Union list of novel foods.

(9) The Commission considers that the requested update of the Union list is not liable to have an effect on human health and that a safety evaluation by the Authority in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary as the requested removal of the particle size requirement for trans-resveratrol from a microbial source does not alter its safety profile because the analytical evidence submitted by the applicant demonstrates that its particle size distribution profile is comparable to that of the chemically synthesised trans-resveratrol which was evaluated by the Authority.

(10) The information provided in the application gives sufficient grounds to establish that the requested changes to the specifications of *trans*-resveratrol are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.

(11) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(12) 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

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

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

Done at Brussels, 22 April 2022.

For the Commission
The President
Ursula VON DER LEYEN

([7]) EFSA Journal 2016;14(1):4368.

ANNEX

In Table 2 (Specifications) of the Annex to Implementing Regulation (EU) 2017/2470 the entry for *trans*-resveratrol is replaced by the following:

Authorised Novel Food	Specifications
'*Trans*-resveratrol	**Description/Definition:** **Synthetic**: Trans-resveratrol is off-white to beige crystals. Chemical name: 5-[(E)-2-(4-hydroxyphenyl)ethenyl]benzene-1,3-diol Chemical formula: $C_{14}H_{12}O_3$ Molecular weight: 228,25 Da CAS No: 501-36-0 **Purity:** Trans-resveratrol: ≥ 98 %-99 % Total by-products (related substances): ≤ 0,5 % Any single related substance: ≤ 0,1 % Sulphated ash: ≤ 0,1 % Loss on drying: ≤ 0,5 % **Heavy metals:** Lead: ≤ 1,0 ppm Mercury: ≤ 0,1 ppm Arsenic: ≤ 1,0 ppm **Impurities:** Diisopropylamine: ≤ 50 mg/kg **Microbial source**: A genetically modified strain of Saccharomyces cerevisiae Appearance: Off-white to slight yellow powder Trans-resveratrol content: Min. 98 % w/w (dry weight basis) Ash: Max. 0,5 % w/w Moisture: Max. 3 % w/w'