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

(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]) establishing a Union list of authorised novel foods was adopted.

(3) Commission Implementing Decision (EU) 2016/1190 ([3]) authorised the placing on the Union market of *trans*-resveratrol as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council ([4]), to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([5]), in capsule or tablet form, for the adult population.

(4) On 31 January 2020, the company DSM Nutritional Products Europe ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to change the conditions of use of the novel food '*trans*-resveratrol'. The applicant requested the modification of the delivery formats for food supplements containing the novel food *trans*-resveratrol, in particular removing the specific delivery formats, capsule or tablet form, as the only allowed forms of the food supplements as listed in the Union list.

(5) The applicant considers that the modification of the delivery formats for food supplements containing *trans*-resveratrol is necessary, as it would allow *trans*-resveratrol to be used in other food supplement forms than capsules or tablets.

(6) There are a number of novel foods currently authorised in food supplements and listed in the Union list of novel foods for which the delivery formats have not been specified. Therefore, the modification of the delivery formats for food supplements containing *trans*-resveratrol would ensure consistency regarding the conditions of use of food supplements, as well as provide more options to food business operators to follow consumer preferences.

([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]) 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).

([4]) 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).

([5]) 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).

(7) The Commission did not request an opinion from the European Food Safety Authority in accordance with Article 10(3) as the change of the conditions of use of the novel food *trans*-resveratrol by removing the specific delivery formats of food supplements is not liable to have an effect on human health. Therefore, it is appropriate to change the conditions of use of the novel food *trans*-resveratrol to authorise its use in any form of food supplements at the previously authorised maximum level.

(8) The maximum level of *trans*-resveratrol in food supplements authorised by Implementing Decision (EU) 2016/1190 and indicated in the Union list of novel foods remains the same. The safety considerations that supported the authorisation of *trans*-resveratrol in food supplements remain valid and the removal of the specific delivery formats of food supplements does not pose safety concern.

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

(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 entry in 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 '*trans*-resveratrol', shall be amended as specified in the Annex to this Regulation.

2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex.

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 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex to Implementing Regulation (EU) 2017/2470, the entry for 'Trans-resveratrol' 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	Data protection
'*Trans*-resveratrol	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the food supplements containing it shall be "*Trans*-resveratrol". 2. The labelling of food supplements containing *trans*-resveratrol shall bear a statement that people using medicines should only consume the product under medical supervision.'		
	Food supplements as defined in Directive 2002/46/EC for the adult population	150 mg/day			