EUROPEAN
COMMISSION

Brussels, XXX
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[…](2016) XXX draft

COMMISSION IMPLEMENTING DECISION

of XXX

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

(Only the English text is authentic)

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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 8 November 2012, the company DSM Nutritional Products Ltd made a request to the competent authorities of Ireland to place *trans*-resveratrol on the market as a novel food ingredient within the meaning of point (f) of Article 1(2) of Regulation (EC) No 258/97.

(2) On 28 June 2013, the competent food assessment body of Ireland issued its initial assessment report. In that report it came to the conclusion that *trans*-resveratrol meets the criteria for novel food ingredients set out in Article 3(1) of Regulation (EC) No 258/97.

(3) On 4 September 2013, the Commission forwarded the initial assessment report to the other Member States.

(4) Reasoned objections were raised within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97.

(5) On 3 April 2014, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment for *trans*-resveratrol as novel food ingredient in accordance with Regulation (EC) No 258/97.

(6) On 11 December 2015, EFSA concluded in its opinion on the safety of synthetic *trans*-resveratrol as a novel food[2], that *trans*-resveratrol used in food supplements intended for adults is safe under the proposed conditions of use.

(7) That opinion gives sufficient grounds to establish that *trans*-resveratrol as a novel food ingredient complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(8) In its opinion, EFSA also indicated that *trans*-resveratrol may interact with specific medicines therefore, it is necessary to inform the consumers when consumed in combination with medicines.

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1 OJ L 43, 14.2.1997, p. 1.

2 EFSA Journal 2016;14(1):4368

(9) Directive 2002/46/EC of the European Parliament and of the Council[3] lays down requirements for food supplements. The use of *trans*-resveratrol should be authorised without prejudice to that legislation.

(10) 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

Trans-resveratrol as specified in the Annex to this Decision may be placed on the market in the Union as a novel food ingredient to be used in food supplements on capsule or tablet form intended for adult population only with a maximum dose of 150 mg per day without prejudice to the provisions of Directive 2002/46/EC.

Article 2

1. The designation of *trans*-resveratrol authorised by this Decision on the labelling of the foodstuffs 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.

Article 3

This Decision is addressed to DSM Nutritional Products Ltd, Heanor Gate Ind. Est. Heanor, Derbyshire, United Kingdom.

Done at Brussels,

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

[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).