COMMISSION IMPLEMENTING REGULATION (EU) 2019/2165

of 17 December 2019

authorising the change of the specifications of the novel food coriander seed oil from Coriandrum sativum 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) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on the updating of the Union list.
- (4) Commission Implementing Decision 2014/155/EU (³) authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council (⁴), the placing on the market of coriander seed oil from *Coriandrum sativum* as a novel food ingredient to be used in food supplements.
- (5) On 2 July 2019, the company Ovalie Innovation ('the applicant') made a request to the Commission to change the specifications of coriander seed oil from *Coriandrum sativum* in accordance with Article 10(1) of Regulation (EU) 2015/2283. The applicant requested to decrease the minimum level of oleic acid from the current 8,0 % to 7,0 %.
- (6) The applicant justified the request by indicating that the change is necessary in order to reflect the natural variation on the levels of oleic acid observed in the *Coriandrum sativum* plant.
- (7) The Commission considers that a safety evaluation of the current application by the European Food Safety Authority ('the Authority') in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. Oleic acid is the natural main component of olive oil. It is also naturally present, at levels identical to the proposed levels for the novel food, in a number of other staple foods that have a long history of safe consumption.
- (8) The proposed change in the levels of oleic acid of coriander seed oil from *Coriandrum sativum* does not alter the conclusions of the safety assessment conducted by the Authority (5) that supported its authorisation by Implementing Decision 2014/155/EU. Therefore, it is appropriate to amend the specifications of the novel food 'coriander seed oil from *Coriandrum sativum*' to the proposed level for oleic acid.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

^(*) 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 2014/155/EU of 19 March 2014 authorising the placing on the market of coriander seed oil as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 85, 21.3.2014, p. 13).

^(*) 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⁾ EFSA Journal 2013;11(10):3422

- (9) The information provided in the application gives sufficient grounds to establish that the proposed changes to the specifications of the novel food 'coriander seed oil from *Coriandrum sativum*' comply with Article 12 of Regulation (EU) 2015/2283.
- (10) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (11) 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 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 novel food coriander seed oil from *Coriandrum sativum*, is amended as specified in 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, 17 December 2019.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex to Implementing Regulation (EU) 2017/2470, the entry for 'Coriander seed oil from *Coriandrum sativum*' in Table 2 (Specifications) is replaced by the following:

Authorised Novel Food	Specifications
'Coriander seed oil from Coriandrum sativum	Description/Definition:
	Coriander seed oil is an oil containing glycerides of fatty acids
	that is produced from the seeds of the coriander plant Cor-
	iandrum sativum L.
	Slight yellow colour, bland taste
	CAS No: 8008-52-4
	Composition of fatty acids:
	Palmitic acid (C16:0): 2-5 %
	Stearic acid (C18:0): < 1,5 %
	Petroselinic acid (cis-C18:1(n-12)): 60-75 %
	Oleic acid (cis-C18:1 (n-9)): 7-15 %
	Linoleic acid (C18:2): 12-19 %
	α-Linolenic acid (C18:3): < 1,0 %
	Trans fatty acids: ≤ 1,0 %
	Purity:
	Refractive index (20 °C): 1,466-1,474
	Acid value: $\leq 2.5 \text{ mg KOH/g}$
	Peroxide value (PV): $\leq 5.0 \text{ meq/kg}$
	Iodine value: 88-110 units
	Saponification value: 179-200 mg KOH/g
	Unsaponifiable matter: ≤ 15 g/kg'