

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1319**of 9 August 2021****authorising changes in the specifications of the novel food Coriander seed oil from *Coriandrum sativum* and amending 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 the Union list of authorised novel foods was adopted.
- (3) 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 in the Union of coriander seed oil from *Coriandrum sativum* as a novel food ingredient to be used in food supplements.
- (4) In October 2017, the company Ovalie Innovation ('the applicant') informed the Commission of its intention to place on the market crude coriander seed oil from *Coriandrum sativum* as a novel food ingredient in accordance with Article 5 of Regulation (EC) No 258/97. Accordingly, the applicant submitted a report of the competent authority of Ireland pursuant to Article 3(4) of Regulation (EC) No 258/97, which, on the basis of the scientific evidence submitted by the applicant, had concluded that the coriander seed oil from *Coriandrum sativum* was substantially equivalent to the coriander seed oil authorised by Implementing Decision 2014/155/EU.
- (5) Commission Implementing Regulation (EU) 2019/456 ⁽⁵⁾ and Commission Implementing Regulation (EU) 2019/2165 ⁽⁶⁾ authorised changes in the specifications of the novel food coriander seed oil from *Coriandrum sativum* to decrease the lowest saponification value from 186 mg KOH/g to 179 mg KOH/g and the minimum level of oleic acid from 8,0 % to 7,0 %.

⁽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 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).

⁽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⁾ Commission Implementing Regulation (EU) 2019/456 of 20 March 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 (OJ L 79, 21.3.2019, p. 13).

⁽⁶⁾ 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 (OJ L 328, 18.12.2019, p. 81).

- (6) On 12 January 2021, the applicant submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to change the specifications of the novel food 'coriander seed oil from *Coriandrum sativum*'. The applicant requested to increase the maximum level of acid value in the coriander seed oil from 2,5 mg KOH/g of oil as indicated in the Union list of novel foods to $\leq 3,5$ mg KOH/g of oil and to modify the colour description from 'slight yellow' to 'yellowish to brown' colour.
- (7) The applicant justified the request by indicating that the change is necessary in order to reflect the natural variation in the visual characteristics of coriander seed oil and in the levels of free fatty acids therein that are measured by titration with potassium hydroxide (KOH) of the seed oil obtained from the *Coriandrum sativum* plant.
- (8) The Commission considers that a safety evaluation by the European Food Safety Authority ('the Authority') of the proposed change of the specifications in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. The increase in the acid value in coriander seed oil from 2,5 mg to $\leq 3,5$ mg KOH/g of oil is comparable to the acid values of other common edible oils with a long history of safe consumption, and is below the upper limit of 4,0 mg KOH/g for edible fats and oils set by the joint Food and Agriculture Organisation of the United Nations and World Health Organisation Food Standards Programme Codex Alimentarius ('FAO/WHO Codex Alimentarius')⁽⁷⁾. On this basis, and for consistency with the FAO/WHO Codex Alimentarius standard, the Commission considers that the limit for the acid value of the coriander seed oil should also be set at 4,0 mg KOH/g. The proposed changes in the specification parameters reflecting the physical appearance of the oil are also comparable to the natural variations observed among practically all edible oils and do not affect its safety or nutritional value.
- (9) The proposed changes in the acid values and the physical appearance of coriander seed oil from *Coriandrum sativum* do not alter the conclusions of the safety assessment conducted by the Authority⁽⁸⁾ that supported its initial authorisation. Therefore, it is appropriate to amend the specifications of the novel food coriander seed oil from *Coriandrum sativum* at the proposed acid level and as regards the physical appearance of the oil.
- (10) 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.
- (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 Union list of authorised novel foods as provided for in Article 6 of Regulation (EU) 2015/2283 and included in the Annex to Implementing Regulation (EU) 2017/2470, referring to the novel food coriander seed oil from *Coriandrum sativum*, shall be 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*.

⁽⁷⁾ CODEX STAN 19-1981, Rev. 2 – 1999.

⁽⁸⁾ EFSA Journal 2013;11(10):3422.

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

Done at Brussels, 9 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

'Authorised Novel Food'	Specifications
Coriander seed oil from <i>Coriandrum sativum</i>	<p>Description/Definition: Coriander seed oil is an oil containing glycerides of fatty acids that is produced from the seeds of the coriander plant <i>Coriandrum sativum</i> L. Yellowish to brown 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: ≤ 4 mg KOH/g Peroxide value (PV): ≤ 5,0 meq/kg Iodine value: 88-110 units Saponification value: 179-200 mg KOH/g Unsaponifiable matter: ≤ 15 g/kg'</p>