



2024/1026

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COMMISSION IMPLEMENTING REGULATION (EU) 2024/1026

of 8 April 2024

**amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food
astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae**

(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 astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae as an authorised novel food.
- (4) Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae has been authorised pursuant to Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽³⁾ for use in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽⁴⁾, intended for the general population.
- (5) Commission Implementing Regulation (EU) 2021/1377 ⁽⁵⁾ amended the conditions of use of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae. In particular, the use level of astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae in food supplements at levels of up to 8,0 mg/day astaxanthin has been restricted to adults and adolescents above 14 years old.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1, ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>.

⁽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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

⁽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, ELI: <http://data.europa.eu/eli/reg/1997/258/oj>).

⁽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, ELI: <http://data.europa.eu/eli/dir/2002/46/oj>).

⁽⁵⁾ Commission Implementing Regulation (EU) 2021/1377 of 19 August 2021 authorising the change of the conditions of use of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 297, 20.8.2021, p. 20, ELI: http://data.europa.eu/eli/reg_impl/2021/1377/oj).

- (6) Commission Implementing Regulation (EU) 2023/1581 ⁽⁶⁾ further amended the conditions of use of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae. In particular, it extended the use of the novel food in food supplements intended for children aged 3 to less than 10 years of age to levels of 23 mg/day of oleoresin (corresponding to up to 2,3 mg/day of astaxanthin), and in food supplements intended for adolescents of 10 to less than 14 years of age to 57 mg/day oleoresin (corresponding to up to 5,7 mg/day of astaxanthin).
- (7) On 20 June 2022, the company Astareal AB ('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 the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae. The applicant requested to modify the content levels for several parameters in the specifications. This concerns the modification of range for astaxanthin monoesters in oleoresin from 79,8-91,5 % w/w of (total) carotenoids to 66,7-91,5 % w/w of (total) carotenoids, the modification of the range of astaxanthin diesters from 0,16-19,0 % w/w of (total) carotenoids to 0,16 to 32,5 % w/w of (total) carotenoids, the modification of range for astaxanthin 9-cis stereoisomer from 0,3-17,3 % w/w of (total) carotenoids to 0,3-30,0 % w/w of (total) carotenoids, and the modification of the range of the protein content from 0,3-4,4 % to 0,0-4,4 %.
- (8) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 26 September 2022, requesting it to provide a scientific opinion on the change of the specifications of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae.
- (9) On 26 September 2023, the Authority adopted its scientific opinion on the 'Safety of a change in specifications of the novel food oleoresin from *Haematococcus pluvialis* containing astaxanthin pursuant to Regulation (EU) 2015/2283' ⁽⁷⁾ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (10) In its scientific opinion, the Authority concluded that the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae is safe under the proposed changes in the specifications, and therefore it is appropriate to amend those.
- (11) The information provided in the application and the Authority's opinion give sufficient grounds to establish that the changes to the specifications of the novel food are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.
- (12) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (13) 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*.

⁽⁶⁾ Commission Implementing Regulation (EU) 2023/1581 of 1 August 2023 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food 'astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae' (OJ L 194, 2.8.2023, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2023/1581/oj).

⁽⁷⁾ EFSA Journal 2023;21(11):8338; doi: 10.2903/j.efsa.2023.8338.

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

Done at Brussels, 8 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

In Table 2 (**‘Specifications’**) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for ‘Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae’ is replaced by the following:

Authorised Novel Food	Specification
‘Astaxanthin-rich oleoresin from <i>Haematococcus pluvialis</i> algae’	Description: Astaxanthin is a carotenoid produced by <i>Haematococcus pluvialis</i> algae. Production methods for the growth of the algae are variable; using “closed” systems exposed to sunlight or strictly controlled illuminated light alternatively open ponds may be used. The algal cells are harvested and dried; the oleoresin is extracted using either super critical CO₂ or a solvent (ethyl acetate). The Astaxanthin is diluted and standardized to 2,5 %, 5,0 %, 7,0 %, 10 %, 15 % or 20 % using olive oil, safflower oil, Sunflower oil or MCT (Medium Chain Triglycerides). Characteristics/Composition: Fat: 42,2-99 % Protein: ≤ 4,4 % Carbohydrate: ≤ 52,8 % Fibre: < 1,0 % Ash: ≤ 4,2 % Specification of Carotenoids % w/w Total Astaxanthins: 2,9-11,1 % 9-cis-astaxanthin: 0,3-30,0 % 13-cis-astaxanthin: 0,2-7,0 % Astaxanthin monoesters: 66,7-91,5 % Astaxanthin diesters: 0,16-32,5 % Beta-Carotene: 0,01-0,3 % Lutein: ≤ 1,8 % Canthaxanthin: ≤ 1,30 % Microbiological criteria: Total aerobic bacteria: < 3 000 CFU/g Yeast and Moulds: < 100 CFU/g Coliforms: < 10 CFU/g E. coli: Negative Salmonella: Negative Staphylococcus: Negative’