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COMMISSION IMPLEMENTING REGULATION

of **XXX**

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use 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 1852/2001¹, 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) 2017/2470² has established a Union list of authorised 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 Council³ for use in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council⁴ intended for the general population.

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>).

Feltkode ændret

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- (5) Commission Implementing Regulation 2021/1377⁵ amended the conditions of use of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae. In particular, the use of the novel food in food supplements containing 40-80 mg of astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae corresponding to levels of astaxanthin up to 8 mg has been limited to adults and adolescents above 14 years of age.
- (6) Commission Implementing Regulation (EU) 2023/1581⁶ 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) Commission Implementing Regulation (EU) 2024/1026⁷ amended the specifications of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae. In particular, it modified the content levels for astaxanthin monoesters in oleoresin to 66,7-91,5 % w/w of (total) carotenoids, astaxanthin diesters to 0,16 to 32,5 % w/w of (total) carotenoids, astaxanthin 9-cis stereoisomer to 0,3-30,0 % w/w of (total) carotenoids, and the protein content to 0,0-4,4 %.
- (8) On 25 March 2021, 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 conditions of use of, astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae. The applicant requested to extend the use of the novel food in dairy analogues, including beverage whiteners, and fruit beverages, except products defined in Part I of Annex I to Directive 2001/112/EC⁸ intended for the general population.

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 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 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 (OJ L, 2024/1026, 9.4.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/1026/oj).

⁸ Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58, ELI: <http://data.europa.eu/eli/dir/2001/112/oj>).

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- (9) On 25 March 2021, the applicant also made a request to the Commission for the protection of proprietary data for two toxicological studies^{9,10} submitted in support of the application.
- (10) On 16 May 2022, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of the extension of use of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae in accordance with Article 10(3) of Regulation (EU) 2015/2283.
- (11) On 29 September 2025, the Authority adopted its scientific opinion on the 'safety of the extension of use of oleoresin from *Haematococcus pluvialis* containing astaxanthin pursuant to Regulation (EU) 2015/2283'¹¹ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (12) In its scientific opinion, the Authority concluded that the proposed change is safe under the proposed conditions of use. Therefore, the scientific opinion gives sufficient grounds to establish that the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae when used under the proposed conditions of use fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (13) In accordance with the Authority's opinion, it is necessary to prevent the concomitant consumption of astaxanthin food supplements by children from 3 years and older, and adolescents under 18 years of age, since such intake would exceed the Acceptable Daily Intake established by the Authority. Therefore, it is appropriate to include additional labelling requirements for the novel food.
- (14) In its scientific opinion, the Authority indicated that the two toxicological studies were not needed for the assessment and reaching the conclusion by the Authority. Therefore, those studies should not be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283.
- (15) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (16) 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.

⁹ Annex 33: a 2D cell culture model with primary hepatocytes from rat, mouse and human performed in 2019.

¹⁰ Annex 34: transcriptomic analysis of gene expression changes after ATX exposure in 2D cultures of rat and human primary hepatocytes performed in 2020

¹¹ [EFSA Journal. 2025;23:e9737 \(https://doi.org/10.2903/j.efsa.2025.9737\)](https://doi.org/10.2903/j.efsa.2025.9737)

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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,

For the Commission
The President
Ursula VON DER LEYEN