

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

## COMMISSION IMPLEMENTING REGULATION

of **XXX**

**authorising the placing on the market of *Haematococcus pluvialis* algal powder containing astaxanthin 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<sup>1</sup>, 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<sup>2</sup> has established a Union list of authorised novel foods.
- (3) On 25 March 2021, the company AstaReal AB ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place *Haematococcus pluvialis* algal powder containing astaxanthin on the Union market as a novel food. The applicant requested the novel food to be used in dairy analogues, including beverage whiteners, and fruit beverages, except products defined in Part I of Annex I to Directive 2001/112/EC<sup>3</sup> intended for the general population.

---

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

<sup>2</sup> 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](http://data.europa.eu/eli/reg_impl/2017/2470/oj))

<sup>3</sup> 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>).

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

- (4) On 25 March 2021, the applicant also made a request to the Commission for the protection of proprietary data for two toxicological studies<sup>4,5</sup> submitted in support of the application.
- (5) On 16 May 2022, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of *Haematococcus pluvialis* algal powder containing astaxanthin as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.
- (6) On 29-30 September 2025, the Authority adopted its scientific opinion on the 'safety of algal meal from *Haematococcus pluvialis* containing astaxanthin as a novel food pursuant to Regulation (EU) 2015/2283'<sup>6</sup> in accordance with Article 11 of Regulation (EU) 2015/2283.
- (7) In its scientific opinion, the Authority concluded that *Haematococcus pluvialis* algal powder containing astaxanthin is safe. Therefore, the scientific opinion gives sufficient grounds to establish that *Haematococcus pluvialis* algal powder containing astaxanthin, 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.
- (8) 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.
- (9) 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.
- (10) *Haematococcus pluvialis* algal powder containing astaxanthin should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. 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.

---

<sup>4</sup> Annex 33: a 2D cell culture model with primary hepatocytes from rat, mouse and human performed in 2019.

<sup>5</sup> Annex 34: transcriptomic analysis of gene expression changes after ATX exposure in 2D cultures of rat and human primary hepatocytes performed in 2020

<sup>6</sup> [EFSA Journal. 2025;23:e9736 \(https://doi.org/10.2903/j.efsa.2025.9736\)](https://doi.org/10.2903/j.efsa.2025.9736)

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

HAS ADOPTED THIS REGULATION:

*Article 1*

1. *Haematococcus pluvialis* algal powder containing astaxanthin is authorised to be placed on the market within the Union.

*Haematococcus pluvialis* algal powder containing astaxanthin shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. 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*.

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*