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

(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) The novel food '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 intended for the general population, as defined in Directive 2002/46/EC of the European Parliament and of the Council ([4]). The maximum authorised levels of the astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae for the general population is currently 40-80 mg per day of oleoresin, resulting in ≤ 8,0 mg astaxanthin per day.

(5) At the time of the establishment of the Union list of authorised novel foods in 2017, the Commission considered that, based on previous two opinions ([5]), ([6]) of 2014 of the European Food Safety Authority ('the Authority'), one on the use of astaxanthin in feed additives as defined in Regulation (EC) No 1831/2003 of the European Parliament and the Council ([7]) on feed additives for animal nutrition, that established an Acceptable Daily Intake ('ADI') of 0,034 mg/kg body weight per day for astaxanthin, and one on the safety of astaxanthin as a novel food ingredient, the intake of astaxanthin from food supplements containing the maximum authorised use levels of up to 8,0 mg per day, may exceed the ADI and may not be in accordance with the conditions set out in Article 7 of Regulation (EU) 2015/2283. The Commission considered that the Union list should be amended to adjust the authorised levels of astaxanthin in light of the 2014 Authority opinions.

([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]) 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).
([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).
([5]) EFSA Journal 2014;12(6):3724.
([6]) EFSA Journal 2014; 12(7):3757.
([7]) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

(6) The Commission also became aware of new scientific evidence in 2017, submitted by business operators during the public consultation of the draft Implementing Regulation establishing the Union list of authorised novel foods, pointing to a considerably higher ADI for astaxanthin than the one previously established by the Authority. In addition, evidence submitted during the same public consultation demonstrated that there already existed a considerable intake of astaxanthin from the normal diet as it is naturally present in some fish and crustaceans.

(7) On 27 February 2018, the Commission, in accordance with Article 29(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([8]) requested the Authority to deliver an opinion on the safety of astaxanthin when used as a novel food in food supplements at levels of up to 8,0 mg/day, taking into account the overall cumulative intake of astaxanthin from all food sources.

(8) On 18 December 2019, the Authority adopted its scientific opinion 'Safety of astaxanthin for its use as a novel food in food supplements' ([9]).

(9) In its scientific opinion, the Authority concluded that on the basis of the new evidence, the ADI for astaxanthin is 0,2 mg/kg body weight per day. Taking into account the astaxanthin ADI and the intake of astaxanthin from the normal diet, the Authority concluded that the intake of the maximum currently authorised levels of up to 8,0 mg/day astaxanthin from food supplements containing astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae is safe for adults and adolescents above 14 years old.

(10) A clear designation of the novel food and a labelling requirement should be laid down for food supplements containing astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae in order ensure that those food supplements are not consumed by children and adolescents aged less than 14 years of age.

(11) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(12) Evidence form the market place seems to indicate that although food supplements containing ≤ 8,0 mg astaxanthin are currently authorised for the general population, in practice they are not used by children and adolsescents but are almost exclusively used by the adult population. In order to limit the administrative burden and to provide business operators with sufficient time to adjust their practices to comply with the requirements of this Regulation, transitional periods should be laid down to cover food supplements containing ≤ 8,0 mg astaxanthin which have been placed on the market or dispatched from third countries for the Union and are intended for the general population, before the date of entry into force of this Regulation. Those transitional measures should take into account the safety of consumers by providing them the information about the appropriate use in line with the requirements of this Regulation.

(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

1. The entry in 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 astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae, is amended as specified in the Annex to this Regulation.

2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

([8]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

([9]) EFSA Panel on Nutrition, Novel Foods and Food Allergens, Scientific Opinion on the safety of astaxanthin as a novel food in food supplements. EFSA Journal 2020;18(2):5993.

Article 2

1. Food supplements containing ≤ 8,0 mg astaxanthin intended for the general population which were lawfully placed on the market before the date of entry into force of this Regulation, may be marketed until their date of minimum durability or use by date.

2. Foods supplements containing ≤ 8,0 mg astaxanthin intended for the general population imported into the Union may be marketed until their date of minimum durability or use by date where the importer of such food can demonstrate that they were dispatched from the third country concerned and were on their way to the Union before the date of entry into force of this Regulation.

3. The food business operators should provide a notice for the food supplements referred to in paragraph 1 to be displayed at the place of sale informing them that those food supplements should not be consumed by infants, children and adolescents below the age of 14 years.

Article 3

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, 19 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex to Implementing Regulation (EU) 2017/2470, the entry for 'Astaxanthin-rich oleoresin from Haematococcus pluvialis algae' in Table 1 (Authorised novel foods) is replaced by the following:

'**Authorised novel food**	**Conditions under which the novel food may be used**		**Additional specific labelling requirements**	**Other requirements**
	Specified food category	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae' The labelling of food supplements containing Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae shall bear a statement that they should not be consumed by infants, children, and adolescents younger than 14 years.'	
'Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae'	Food Supplements as defined in Directive 2002/46/EC, excluding infants, young children, children, and adolescents younger than14 years	40-80 mg/day of oleoresin, resulting in ≤ 8 mg astaxanthin per day		