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'

(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 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) The novel food 'astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae' has been authorised in accordance with 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. The maximum authorised levels of the novel food is 40–80 mg/day of oleoresin, resulting in ≤ 8 mg astaxanthin per day.

(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 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. The amendment was based on an opinion of the European Food Safety Authority ('the Authority') 'Safety of astaxanthin for its use as a novel food in food supplements' ([6]), which concluded on the safety of the levels up to 8 mg of astaxanthin only for the population above 14 years of age.

([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]) 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).

([6]) 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.

(6) On 15 December 2022, the company Natural Algae Astaxanthin Association ('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 food supplements intended for children 3 to less than 10 years of age at levels of 23 mg/day of oleoresin (corresponding to up to 2,3 mg/day of astaxanthin), and to food supplements intended for adolescents aged 10 to less than 14 years of age containing 57 mg/day oleoresin (corresponding to up to 5,6 mg/day of astaxanthin).

(7) The Commission considers that the requested change in the conditions of use of astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae is not liable to have an effect on human health and that a safety evaluation by the Authority in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. Taking into account the Acceptable Daily Intake ('ADI') of astaxanthin of 0,2 mg/kg body weight per day and the intakes of astaxanthin from the background diet as set out in the opinion of the authority published in 2020, the intake of astaxanthin from food supplements as proposed by the applicant would result in overall intakes of astaxanthin that do not exceed the ADI.

(8) The information provided in the application gives sufficient grounds to establish that the changes in the conditions of use of astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae, are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.

(9) In line with the change in the conditions of use of food supplements containing various levels of astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae depending on the targeted age groups of the population, it is necessary to inform consumers by appropriate labelling that food supplements containing the novel food are not to be consumed by the groups of the population they are not intended for, and are not to be consumed by infants and young children. In addition, the Commission considers appropriate to lay down additional labelling requirement in order to prevent concomitant consumption of astaxanthin food supplements, which is likely to exceed the ADI established by the Authority.

(10) In order to limit the administrative burden and to provide business operators with sufficient time 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 older than 14 years of age, 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.

(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 Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

1. Food supplements containing ≤ 8,0 mg astaxanthin intended for the general population older than 14 years of age, 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. Food supplements containing ≤ 8,0 mg astaxanthin intended for the general population older than 14 years of age, 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.

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, 1 August 2023.

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
'Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae	*Specified food category*	*Maximum levels of astaxanthin*	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: (a) if other food supplements containing astaxanthin esters are consumed on the same day (b) by infants and young children under 3 years of age (c) by infants and children under 10 years of age (*) (d) by infants, children and adolescents under 14 years of age (*).	
	Food supplements as defined in Directive 2002/46/EC excluding infants and young children	2,3 mg astaxanthin per day for children 3 to less than 10 years of age		
		5,7 mg astaxanthin per day for adolescents 10 to less than 14 years of age		
		8 mg astaxanthin per day for general population older than 14 years of age		

(*) Depending on the age group the food supplement is intended for.'