# Commission Implementing Regulation (EU) 2018/1132 of 13 August 2018 authorising the change of the designation and specific labelling requirement of the novel food synthetic zeaxanthin 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)

## COMMISSION IMPLEMENTING REGULATION (EU) 2018/1132

## of 13 August 2018

## authorising the change of the designation and specific labelling requirement of the novel food synthetic zeaxanthin 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)] was adopted, which establishes a Union list of authorised novel foods.

(3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to submit a draft implementing act authorising the placing on the Union market of a novel food and updating the Union list.

(4) Natural zeaxanthin is a component of the normal human diet as it is found in many fruits and green vegetables as well as in egg yolk. It is also currently used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[(3)].

(5) Commission Implementing Decision 2013/49/EU[(4)] authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council[(5)], the placing on the market of synthetic zeaxanthin as a novel food ingredient in food supplements at the maximum intake of up to 2 mg per day. The designation of synthetic zeaxanthin authorised by Implementing Decision 2013/49/EU on the labelling of the foodstuffs containing it is ‘synthetic zeaxanthin’.

(6) On 23 February 2018, the company DSM Nutritional Products Europe ('the Applicant') made a request to the Commission to authorise the amendment of the designation and of the specific labelling requirements for synthetic zeaxanthin within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requests the deletion of the term 'synthetic' from the designation of the novel food as listed in the Union list and from the labelling of foodstuffs containing it.

(7) The Applicant considers that the change of the designation and the labelling requirements of zeaxanthin is necessary to alleviate any potential negative economic impact that the use of the term 'synthetic' on the labelling of food supplements containing synthetic zeaxanthin may cause due to the negative connotation of the term 'synthetic'. The Applicant also claims that such potential negative economic impact is most probably not experienced by economic operators placing on the market food supplements containing authorised synthetic novel foods which do not carry the term 'synthetic' on their labelling.

(8) There are a number of synthetic substances currently authorised and listed in the Union list of novel foods, of which the counterparts from natural origin exist, and both forms are used in food supplements. However those synthetic substances are not designated as synthetic in the Union list and are not labelled as such. The change in the designation and labelling of synthetic zeaxanthin will ensure consistency with the designation and labelling of those synthetic substances.

(9) There are no changes in the proposed uses and use levels of zeaxanthin when used as an ingredient in food supplements, the safety considerations that supported the authorisation of synthetic zeaxanthin by Implementing Decision 2013/49/EU remain valid and therefore this change does not pose any safety concerns. Taking into account these legitimate factors, the proposed changes comply with Article 12(1) of Regulation (EU) 2015/2283.

(10) The implementation of the new labelling requirement in accordance with this Implementing Regulation might involve changes for the business operators who currently place synthetic zeaxanthin on the market. Therefore, it is appropriate to provide for a transitional period.

(11) Directive 2002/46/EC lays down requirements on food supplements. The change of designation and of specific labelling requirement for zeaxanthin should be authorised without prejudice to that Directive.

(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*

1 The entry in the Union list of authorised novel foods as provided for in Article 8 of Regulation (EU) 2015/2283 referring to the substance zeaxanthin shall be amended as specified in the Annex to this Regulation.

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

3 The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC.

*Article 2*

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

*Article 3*

Food supplements containing synthetic zeaxanthin and complying with Regulation (EU) 2015/2283 as applicable before the entry into force of this Regulation may be placed on the market until 3 September 2019 and may remain on the market until exhaustion of stocks.

*Article 4*

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, 13 August 2018.

*For the Commission*

*The President*

Jean-Claude JUNCKER